REVIEW OF ARTIFICIAL BARRIERS TO U.S. AGRICULTURAL TRADE AND FOREIGN FOOD ASSISTANCE

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

FIRST SESSION

MARCH 26, 2003

Serial No. 108–1

Printed for the use of the Committee on Agriculture
www.agriculture.house.gov

U.S. GOVERNMENT PRINTING OFFICE

86–580 PDF WASHINGTON : 2003

For sale by the Superintendent of Documents, U.S. Government Printing Office
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REVIEW ARTIFICIAL BARRIERS TO U.S. AGRICULTURAL TRADE AND FOREIGN FOOD ASSISTANCE

WEDNESDAY, MARCH 26, 2003

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The committee met, pursuant to call, at 10:10 a.m., at 1300 Longworth House Office Building, Hon. Bob Goodlatte (chairman of the committee) presiding.

Present: Representatives Pombo, Smith, Everett, Lucas of Oklahoma, Moran, Jenkins, Gutknecht, Osborne, Graves, Janklow, Burns, Bonner, Chocola, Nunes, Stenholm, Peterson, Dooley, Holden, Etheridge, Baca, Ross, Case, Alexander, Ballance, Pomeroy, Boswell, Lucas of Kentucky, Thompson of California, and Udall.

Staff present: William E. O'Conner, Jr., staff director; Brent Gattis, deputy staff director; Lynn Gallagher, Elyse Bauer, John Goldberg, Elizabeth Parker, Callista Gingrich, clerk; Kellie Rogers, Jason Vaillancourt, Ryan Weston, Pamilyn Scott, Jon Hixson, Vernie Hubert and Chris Church.

OPENING STATEMENT OF HON. BOB GOODLATTE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF VIRGINIA

The CHAIRMAN. Good morning. This hearing of the House Committee on Agriculture to review artificial barriers to agricultural trade and foreign food assistance will come to order. I have an opening statement.

The purpose of our hearing is to receive testimony regarding the extent and impact of artificial barriers to trade in agricultural products produced through biotechnology. The artificial barriers that face such agricultural products range from banning the product from entry into foreign markets, denying farmers the opportunity to improve their crops with such products, and preventing food from being delivered to hungry families in developing countries.

The United States is the leader in agricultural biotechnology. Modern agricultural technology is one of the most promising developments in modern science. Used in collaboration with traditional methods, it can raise crop productivity, increase resistance to pests and disease, develop tolerance to adverse weather conditions, improve the nutritional value and taste of some foods, enhance the

durability of products during harvesting and shipping, and create new markets for specially tailored crops.

For example, in the early 1990's, a ring spot virus decimated Hawaii's $17 million papaya crop, which was the State's fifth largest crop. However, following 20 years of research by university scientists, in 1997, the Federal Government approved a process in which a gene was inserted into the plants that made them resistant to the ring spot virus. Hawaii's papaya crop rebounded due to biotechnology research.

This technology is not only being used in the United States, but it is also being developed for use in East Africa, Bangladesh, and parts of Asia. Other research going on includes building a gene into rice that produces more beta carotene, a precursor to vitamin A. Up to half a million children per year go blind due to vitamin A deficiency. Other products, like beta carotene, enhanced mustard oil in India and and beta carotene enhanced maize in Africa are also being developed. New varieties of high protein corn are being developed that could help chronic deficiencies in children in Asia, Africa, and Latin America.

Also, researchers are now working to build a vaccine into bananas for hepatitis B. This edible vaccine could be delivered at a fraction of the cost of conventional treatment. However, the knowledge and appreciation of these benefits is not shared by all. In the United States, regulations for biotechnology foods are based on the principle that they are substantially equivalent to conventional foods. Therefore the existing regulations are appropriate for biotechnology foods and special labeling is not required. An exception to this applies if there is a significant difference, as in the case of the presence of an allergen.

Other countries require special treatment of biotechnology foods. The European Union, Japan, South Korea, China, Australia, and New Zealand either have or are in the process of establishing mandatory labeling of these foods. Additionally, the European Union maintains what serves as a ban on new approvals of biotechnology. Even David Byrne, the European Union Commissioner for Health and Safety, warned European governments to "end their foot-dragging over approval of new genetically modified crops."

We have, however, seen how the European moratorium may have influenced some developing countries to reject much needed U.S. food aid because the shipments contained corn produced with biotechnology. These corn products are the same products that Americans have been consuming for years. The situation in Zambia should be of concern to all of us, since it appears that some developing countries have adopted the European position on biotechnology. The politicizing of agricultural biotechnology should end so that we can return to providing food aid to the hungry as soon as possible.

Dr. Norman Borlog, known as the architect of the Green Revolution and a 1970 Nobel Peace Prize winner, once said that "the affluent nations can afford to adopt elitist positions and pay more for the food produced by so called natural methods; the 1 billion chronically poor and hungry people of this world can not. New technology will be their salvation, freeing them from obsolete low yielding and more costly production technology."

America's farmers and ranchers produce the safest and most bountiful food supply in the world. Their goal is to share this bounty with those who need it most, while at the same time, having access to markets around the world.

At this time it is my pleasure to recognize the ranking democrat on the committee, the gentleman from Texas, Mr. Stenholm.

OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM. Thank you, Mr. Chairman, and I commend you for calling this hearing on a very timely issue.

We have repeatedly heard the explanation that the European Union maintains its ban on new approvals of biotech products because European consumers are unwilling to accept biotechnology due to safety concerns. That explanation disappoints me. As the Farm Bureau points out in their testimony this morning, there are no peer reviewed scientific risk assessments—I repeat—there are no peer reviewed scientific risk assessments that conclude that food products of agricultural biotechnology are inherently less safe than their traditional counterparts.

Bioengineered crops in the United States are rigorously reviewed for environmental and food safety by USDA, EPA, and FDA. Food safety reviews of bioengineered crops focus on the safety of the newly introduced trade, on the safety of the whole food, and consider issues including toxicity, allergenicity, nutritional content, and antibiotic resistance. Our forward looking regulatory system has not only ensured the safety of our food supply; it has allowed the development of technologies that have improved our food supply and lowered the cost of food production. Besides lowering cost, biotechnology has the potential to reduce crop risks and improve food security in developing countries. Examples include USA products in Africa to improve production of peas and bananas.

Regulations based on protectionism, instead of science, have a chilling effect on research and the adoption of biotechnology. When there is uncertainty that a product of biotechnology will be accepted, farmers are reluctant to adopt the product despite its proven safety and benefits.

I believe that the United States and the European Union have a responsibility, as developed nations, to lead by example in developing regulatory systems that not only promote safe food, but also promote a better and more secure food supply. And I am disappointed that Europe has so far been unable to construct a science-based regulatory system for food that encouraged development of new technologies that can benefit developed and developing countries around the world.

Thank you, Mr. Chairman. I look forward to hearing from our witnesses today.

The CHAIRMAN. Thank you, Mr. Stenholm.

Any other statements from Members will be accepted for the record.

[The prepared statements follow:]

PREPARED STATEMENT OF HON. NICK SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

I want to thank Chairman Goodlatte and Ranking Minority Member Stenholm for holding this hearing to review artificial barriers to U.S. agricultural trade and foreign food assistance. Unfortunately, an increasingly contentious debate between the United States and Europe over biotechnology is now distorting trade worldwide. Hopefully, this hearing will provide a forum in which we can discuss ways to ensure that decisions on the worldwide trade and regulation of GM crops are science-based as opposed to politically-motivated.

Advances in the genetic engineering of crops have allowed us to harnesses the forces of nature in a more precise, and ultimately safer way than ever before. Traditional crop varieties are the product of selective and experimental cross-breeding, where scientists have sought to enhance desirable characteristics—such as pest resistance, greater tolerance to heat or cold, or increased yield. This process combines 20,000 to 30,000 genes from each parent, can take a great deal of time, and often causes other less desirable changes. Genetic engineering allows us to incorporate specific genes with known characteristics to achieve the desired results with more precision, and fewer unintended effects. As a result, bioengineered crops and pharmaceuticals have great potential, especially in developing nations. Biotechnology can produce crops that will grow readily in places where it is difficult or impossible to plant now. For developing nations biotechnology can also improve nutrition and health by adding vitamins and immunizing agents to food.

The U.S. agriculture industry's embracement of scientific advancements in GM crop development has further contributed to the United States producing the safest and most bountiful food supply in the world. Unfortunately, the European Union and other nations have been opposed to GM crops based on misleading, scientifically-unjustified food safety and environmental risk concerns. Because GM crops face far more strenuous regulation and review from the FDA, USDA, and EPA than new cross-bred varieties, they most likely are safer for consumers. Furthermore, many GM varieties also generate environmental benefits by reducing the need for herbicides, pesticides, and fertilizers that can become contaminants. A second reason that Europeans oppose GM crops is that they fear that our lead in biotechnology will reduce production costs and allow American farmers to sell high quality food cheaper than our competitors.

The conflict is now escalating to other parts of the world. Actions taken by the Europeans have pressured African and South American countries not to plant GM crops, telling them that their export products will not be accepted. As a result, Zambia has even rejected emergency relief for its starving population because some food grain could be planted and endanger future exports. Aside from the immediate need for food, this is especially unfortunate because GM crops show some of their greatest potential in Africa and developing nations around the world.

As chairman of the Subcommittee on Science Research on the House Science committee, I will be holding a hearing to specifically review the potential of GM crops to assist developing nations to move toward greater self-sufficiency and how the Government can help. It is imperative that we examine why African nations to date have largely not benefitted from biotechnology and how to best encourage such nations to make regulatory, trade, research, and even planting decisions based on sound science and not on politics.

Science has been enormously important in keeping the world fed. People are better fed today than ever before in human history despite enormous population growth. The Green Revolution of the 1960's and 1970's brought highly productive hybrids into use all over the world, averting famines and increasing living standards. Biotechnology now builds on the Green Revolution to ensure that the world's food supply continues to grow as fast as population.

Bioengineering opponents emphasize the very small and well regulated risks of GM crops while ignoring the immediate risk of starvation and malnutrition in many parts of the world. That attitude is tolerable in developed counties, but it is a betrayal of that majority of the world that struggles to feed itself through periods of war, natural disaster, and economic crisis. Utilizing regulations for GM crops as artificial barriers to agricultural trade and foreign food assistance is detrimental to everyone involved from the American farmer to the starving, undeveloped nations most in need of the promise that GM crops hold for short-term food assistance and long-term agricultural development.

PREPARED STATEMENT OF HON. FRANK D. LUCAS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

Thank you Mr. Chairman for holding this hearing and for providing me with the opportunity to comment on its importance to Oklahoma and its agricultural producers.

In my area of Oklahoma, wheat and cattle production is the driving economic force. Few industries can claim to be as important to Oklahoma as agriculture. Today, we are going to hear numerous witnesses explain how countries may be hiding behind false assumptions and little to no scientific evidence in order to keep U.S. products of biotechnology from being imported into their countries.

Why should this concern me? It concerns me because nearly 50 percent of the wheat in the United States is bound for export markets! It is important to note that while no U.S. wheat is currently produced using modern biotechnology methods, there is already one approved product and no doubt will be many more that will help U.S. producers enhance productivity and profitability.

U.S. institutions such as USDA and FDA have proven time and again that the approved U.S. products of biotechnology have met and exceeded scientifically sound safety standards. It is imperative that the United States help foreign governments develop sound institutions of food and agriculture safety so that those countries' consumers can strongly believe that government approved food products are safe—whether grown by traditional or modern methods of biotechnology.

My subcommittee plans to hold hearings to explain how the USDA, FDA, and EPA have worked together to provide sound testing and safety measures. We will also have hearings to explain the benefits to producers and consumers alike.

We can not afford to have U.S. markets closed by false assumptions and must work hard to show that U.S. remains a leader in agricultural production with safest food supply in the world.

I look forward to today's testimony.

PREPARED STATEMENT OF HON. FRANK BALLANCE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Thank you Chairman Goodlatte and Ranking Member Stenholm for your diligent efforts on this committee.

Mr. Chairman, for hundreds of years, the American farmer has provided for the American People, and in recent years, has provided for the entire world. American produced food helps reduce our worsening balance of trade and feeds hungry people throughout the developing world.

The issue of the exportation of genetically modified foods continues to be of concern to North Carolinians, in particular to producers of corn. I am troubled by the increasing number of barriers to exporting to other nations that are forcing our farmers to struggle even more. By improving the options available to exporters of our produce, we will be helping both our rural and urban communities.

I am also concerned that America may not be doing enough to educate foreign countries about genetically modified foods. Many poor nations lack infrastructure to determine if food is safe. With images on television of epidemics like Mad Cow Disease, African leaders are very hesitant to go on the findings of the food safety inspection and research services of another nation. With many countries in Africa dealing with HIV/AIDS, their leaders are hesitant to introduce an item into the food supply that they suspect could further complicate health problems.

Without adequate information, it is no wonder why countries have come to different conclusions about the food products they allow into their country. However, with adequate resources and information, these concerns may be alleviated and the good work done by world aid programs will continue unimpeded.

Mr. Chairman, I thank the committee for drawing attention to this important issue, and look forward to working with you and the ranking member on this critical matter.

The CHAIRMAN. It is now my distinct privilege to invite Speaker Dennis Hastert to the witness table. Speaker Hastert has been a leader on biotechnology issues and represents a State, Illinois, that has benefited greatly from this technology, but is also concerned about some of the developments that have occurred around the world. Speaker Hastert, we are honored to have you with us today and we would be delighted to receive your testimony.

STATEMENT OF HON. J. DENNIS HASTERT, SPEAKER, U.S. HOUSE OF REPRESENTATIVES, FROM THE STATE OF ILLINOIS

The SPEAKER. Thank you, Mr. Chairman. It is an honor to be here, and I have a prepared statement that I think in respect for your time, I will submit that to the record. I just want to make a brief comment on this and then open it up for some questions.

First of all, I want to recognize Leon Corzine, who is a former Illinois Corn Growers president. He is here today to testify and I appreciate his effort. And I also want to just be very honest, that my district in Illinois has some of the top producing counties in the Nation, for corn production and soybean production. So I have an interest in what happens here, but I think we all have an economic interest that we can take our products and not only develop those products so they are real quality products, but able to sell those products overseas.

Forty percent of the crop product in my district in Illinois is exported overseas. Right now, we are seeing that protectionism has a new guise. As we speak, the WTO is discussing a framework of negotiations in the Doha round of trade talks with the objective or reducing worldwide tariffs on agricultural products. As you know, world agricultural tariffs average about 62 percent. Well, here in the United States, agricultural tariffs average about 12 percent. We have the best technology, we have the best ability to produce, and we have the best product to put on a world market. The problem is that we are being artificially stopped from being able to move our products overseas.

And let me go back. I used to sit on the Commerce Committee. I never had the great honor of sitting on the Agriculture Committee, but I was on the Commerce Committee, and every year we would come up with food standards. And folks were coming in and say, well we have to adhere to the Delaney clause, so we have to use less insecticides or pesticides. We have to also make sure that we don't put too many herbicides on the soil because it leeches out and causes problems to our environment. And then folks would come in and say, you can't use too many fertilizers, because they leech out and they cause environmental problems. So over the years, what we have tried to do is to use less herbicides, less pesticides, and less fertilizer, and grow a better product.

On my little farm in Illinois, we used as many environmentally friendly methods as possible. We do no-till and all the other things that you have to do. But what we are faced with as we do a better job in meeting the needs of the environment, and meeting the needs of consumers, and making sure that our food product is pure, we face continual resistance in selling our food products overseas because we are technologically superior. The whole idea of GMO didn't happen yesterday. I happen to have a company called Dekalb Seed in my area. I grew up and my dad was a farm service dealer. I spent a lot of time in the back of a feed truck unloading feed bags and seed bags. And even back then we were making a better soybean product and corn product, as we were doing hybrids. Well, we have taken that to a level that we can produce a product that is superior.

I happened to be in South Africa a couple of years ago and went out to a testing station where they had a product that—an Amer-

ican company was there and had a product that had been GMO modified. It stood about 4 feet taller than the native corn. It was free of rootworm, and corn bore, and different types of insects that would feed upon that product. It was a good, pure, clean product, and people that grow 5, or 6, or 7 acres of corn, they would actually get a product that they could feed their families and put on the market. They could sell the excess; where the other folks, they could barely make a living.

Now, we have a problem in my view with the European Union. The European Union has, in my opinion, set up artificial barriers that it is almost impossible for us to compete with our products overseas. As a matter of fact, they have had a situation where we haven't been able to get our seeds overseas into the European market; not because the farmers don't want it. It is not because European farmers don't want me to be more competitive, but the bureaucracy that makes up the EU and has its ties in the World Trade Organization has been able to stop us from doing it.

And I have to relate just a very short story. I was with about two members of your committee, and we were in Europe, and it was before Christmas. We were in Poland, Portugal, and Italy, and we had the chance to encounter the agriculture minister of Italy, who has been an advocate of holding GMO products out of the EU. And as a long discussion that I think probably stretched over about 3 hours, after we debated with him, there wasn't any real science that he could hold it out, there wasn't any real health problems that they could hold out GMO products, that there wasn't any other economic problems that they had a good reason to hold out GMO products; but basically, that they wanted to protect their markets. They didn't have a more productive product, and partly, I think, you have agricultural economists that can get into it deeper than I can, but basically, what their problem is, they didn't want their farmers to be more productive because then they had to subsidize them more and it became money out of their pockets.

Also, it really came down to the argument, and the gentleman said we just need to stick with our traditional methods, and people, our consumers, ought to have everything labeled, that they understand what this product is about and what goes into it, so that we can put it on the shelves and say this product has been genetically modified. Well, there are a lot of things that we could probably label, too, and I won't get into that. But what we need to do is make our product more competitive.

I have asked, along with other members of this committee and other members of our Congress, to ask our trade ambassador to go to World Trade and actually file suit that we can get our GMO products into those markets. That will take some time, but this is an issue that is longstanding, an issue that is important for our agricultural viability, important for our ability to be competitive in the long term, and be viable to sell our products.

In U.S. dollars, the ability for the EU to hold out U.S. corn products costs us about $300 billion a year, and you can go on and on. So it does affect our ability to trade, it does affect our economic well being, and it does affect the ability to keep family farms together.

So I thank you. I thank you for taking the time and looking at this issue. There will be much more expert testimony than mine on this issue. I would like to submit my written testimony for the record, and Mr. Chairman, I would be happy to take any questions.

[The prepared statement of Speaker Hastert follows:]

STATEMENT OF HON. J. DENNIS HASTERT, SPEAKER, U.S. HOUSE OF REPRESENTATIVES

Thank you Mr. Chairman for the opportunity to appear before the committee today to comment on the artificial barriers to U.S. agriculture trade. I appreciate your committee's leadership on this important issue, and thank you for holding this hearing.

Mr. Chairman, protectionism has a new guise. As we speak, the WTO is discussing a framework for negotiations in the Doha round of trade talks with the objective of reducing worldwide tariffs on agriculture products. As you know, world agricultural tariffs today average about 62 percent, while U.S. agricultural tariffs average 12 percent.

While these negotiations represent an important step towards the free exchange of farm goods, there is a more imminent threat to the cause of free trade—the use of non-tariff barriers.

Over the last few years, we have seen country after country implementing protectionist trade policies under the cloak of food safety—each one brought on by emotion, culture, or their own poor history with food safety regulation.

We have seen policies such as those imposed by the European Union and other countries on agricultural biotechnology; the use of geographical indications to protect agricultural goods; and the taxation of goods that include agricultural products, such as the tax on soft drinks that contain high fructose corn syrup in Mexico.

Simply put, non-tariff protectionism is detrimental to the free movement of goods and services across borders. We all know that free trade benefits all countries. However, free trade will be rendered meaningless if it is short-circuited by non-tariff barriers that are based on fear and conjecture—not science.

One particular issue I would like to focus on today is the use of non-tariff barriers to limit the trade and use of genetically-modified products.

As the Representative of the 14th district in Illinois, my district currently covers portions of eight counties, including four of the top 25 corn-producing counties, and three of the top 50 soybean-producing counties in the Nation. The State of Illinois is the second-largest producing State of both corn and soybeans in the country. Forty percent of this production currently goes to exports, valued at approximately $2.7 billion per year.

U.S. agriculture ranks among the top U.S industries in export sales. In fact, the industry generated a $12 billion trade surplus in 2001, helping mitigate the growing merchandise trade deficit. It is important to realize that 34 percent of all corn acres and 75 percent of all soybean acres are genetically modified.

And what exactly are we talking about when we say "genetically modified?" The EU and other countries would have you believe this is a new and special type of food, questionable for human consumption. In fact, since the dawn of time, farmers have been modifying plants to improve yields and create new varieties resistant to pests and diseases. Why would we want to snuff out human ingenuity that benefits farmers and consumers alike?

Such advancements have been achieved by taking plants with desirable traits and crossbreeding them. In fact, almost all of today's commercial crops are now distant cousins from the plants that first appeared in this country. Biotechnology is merely the next stage of development in this age-old process.

As this committee is well aware, the European Union has had an indefensible moratorium on genetically-modified products in place for over four years with no end in sight. This is a non-tariff barrier based simply on prejudice and misinformation, not sound science. In fact, their own scientists agree that genetically modified foods are safe.

We should all be concerned that this irrational policy is spreading. China, for example, has developed new rules for the approval and labeling of biotech products. An overwhelming portion of the entire $1 billion U.S. soybean export crop is genetically modified. Although implementation has been delayed, such a labeling program would certainly result in higher food costs for consumers and higher production costs for farmers.

And what exactly are we labeling? There is general consensus among the scientific community that genetically modified food is no different from conventional food.

What's different is not the content of the food, but the process by which it is made. Labeling genetically modified products would only mislead consumers and create an atmosphere of fear.

It's important for the public to know that the U.S. government has safely regulated biotechnology since its inception over 30 years ago. And with the rapid evolution of plant biotechnology in the early 1980s, additional regulation was added. Ask any American farmer about Government regulation and not one will tell you that they are under-regulated.

Biotechnology products are screened by at least one, and often by as many as three, federal agencies. From conception to commercial introduction, it can take up to 10 years to bring a biotech variety to market. Throughout the process, the public has ample opportunity for participation and comment, and data on which regulatory decisions are based are readily available.

Still, regardless of the overwhelming evidence to the contrary, bans on genetically modified products continue to persist and multiply. The worldwide impact has been staggering.

The current EU moratorium on genetically-modified products has translated into an annual loss of over $300 million in corn exports for U.S. farmers. More disturbing is the recent trend in Africa, where several nations have rejected U.S. food aid because the shipments contained biotech corn. This based solely on the fear that EU countries will not accept their food exports if genetically modified seeds spread to domestic crops.

These actions by our trading partners have consequences. U.S. farmers are already beginning to plant more non-biotech seeds. This trend will increase farmers' cost of production as well as increase the damage from harmful insects. In fact, the U.S. Environmental Protection Agency has recently approved a corn technology that will allow the commercialization of the first corn designed to control rootworm—a pest that costs U.S. farmers approximately $1 billion in lost revenue per year. It is absurd to think that farmers would not be able to take advantage of this technology.

Clearly, the long-term impact of these policies could be disastrous for U.S. farmers in terms of competitiveness and the ability to provide food for the world's population. Addressing world hunger is particularly critical when approximately 800 million people are malnourished in the developing world, and another 100 million go hungry each day. Biotechnology is the answer to this pressing problem. Farmers can produce better yields through drought-tolerant varieties, which are rich in nutrients and more resistant to insects and weeds, while those in need reap the benefits.

As Hassan Adamu, Minister of Agricultural and Rural Development for Nigeria, stated in a September 2000 Washington Post Op-ed:

"Agricultural biotechnology . . . holds great promise for Africa and other areas of the world where circumstances such as poverty and poor growing conditions make farming difficult. Fertilizer, herbicides, pesticides, machinery, fuel and other tools that richer nations take for granted as part of their farming regimen are luxuries in poorer countries. These circumstances demand unique agricultural solutions, and many have been made available through the advances in agricultural biotechnology."

As you can see, halting or even slowing down the development of this technology could have dire consequences for countries where populations are growing rapidly and all arable land is already under cultivation.

It is my opinion that official WTO action is the only course that would send a clear and convincing message to the world that prohibitive policies on biotechnology which are not based on sound science are illegal. In fact, I would like to thank the members of this Committee who recently joined me in sending a letter to the President in support of WTO action—these are policies which simply must not be allowed to persist.

The EU should immediately lift its unfair moratorium and evaluate biotechnology products using a scientifically-based process with definitive timeframes for approval. It should also keep U.S. exporters informed about developments in the approval process. And if these procedures require additional time, information, or reviews by different committees, they should be justified, officially adopted and communicated to the affected industry. Only then will we have an international process which can benefit both consumers and producers worldwide.

I greatly appreciate the chance to offer my thoughts on this important issue. It is my opinion that the U.S. Government should immediately take a case to the WTO regarding the current EU moratorium. After all, the price of inaction is one we can no longer afford to pay. With that said, I look forward to continue working with my

colleagues, the administration and the committee to eliminate all barriers to free trade.

The CHAIRMAN. Thank you, Mr. Speaker. Without objection, I would also ask that the letter you referred to that I also signed, as well as a number of other members of the House signed, to the President be made a part of the record as well. I want to thank you for your excellent presentation that I think is right on and is very, very helpful to this effort.

I have asked some of the committee staff whom you know and who go back a long way with this committee, and we cannot recall the last time that a Speaker of the House has testified before the House Agriculture Committee. So not only are we honored to have you with us, but also, we think it signifies the importance of the issue; certainly, the importance that you place on it, and we share that concern.

I wanted to follow up on your comments about the possibility of bringing a challenge to the European Union moratorium with the World Trade Organization, and I wondered what your view is about the argument that a WTO challenge would be counter-productive, might harden European opposition to biotechnology produced foods and not result in increased market access for biotechnology produced products.

The SPEAKER. Well, my view, I guess I am just kind of an old hard-nose on this, that if you back away, you let them have their way, they will have their way. And it might be GMO today, it might be another issue tomorrow, but if they think they can back you down with red herring reasons as they drag it across the path, there will be no end to our ability not to be able to forthrightly trade and move our products overseas. I think you need to challenge them. I think you need to go nose and nose, because only when they are confronted with facts and truth and legal reality do they begin to back down. I think we need to go full force. That is my opinion.

The CHAIRMAN. Well, thank you. I certainly agree with that. And it is, I think, a problem not just in Europe, but it is now beginning to have repercussions elsewhere in the world. That is really one of the subjects of this hearing, related to famine in Africa, which we will get into more detail later. I think we also need to stress the point that we are not trying to get anybody to eat something they don't want to eat. We want to make sure we are treated fairly to have the opportunity to introduce our products into Europe, sell them, let people make a decisions for themselves, and at the same time, we want to be able to sell non-GM products there as well. Some of the considerations the Europeans are pursuing regarding labeling of these products are making it hard to even do that.

The SPEAKER. Well, Mr. Chairman, you are right. I think consumers need to have those choices and that is what our economy is based on, and hopefully, that is what a free market economy in Europe is based on. We have seen different indications and pressuring of countries, and that is one of the problems we see developing in the EU, that all of a sudden, if you are part of the EU, you can only buy EU, you can't buy outside of the country. But the fact of going back to genetically modified corn or soybeans, we have been eating these products for 30 years, and they are a better prod-

uct. They are a superior product and people are using reasons that aren't justified to stop these products coming into their borders.

The CHAIRMAN. Absolutely right. It is now my pleasure to recognize the ranking member from Texas, Mr. Stenholm, for any questions he might have.

Mr. STENHOLM. No questions. I just appreciate, Mr. Speaker, you coming. I appreciate your interest in the issue.

The SPEAKER. Thank you.

The CHAIRMAN. I understand that you need to move on to attend other business, and we want to again thank you greatly for your participation today.

The SPEAKER. Thank you, Mr. Chairman. I thank the committee. Thank you very much.

The CHAIRMAN. The next panel is going to comprise Congressman Frank Wolf and Congresswoman Jo Ann Emerson, and my understanding is that neither of them are here yet. In the interest of time I think we should proceed to the next panel and we will give Congressman Wolf or Congresswoman Emerson an opportunity when they do arrive.

At this time, we would like to welcome our third panel to the table: Dr. John Kilama, president of Global Bioscience Development Institute, and Dr. Calestous Juma, director of the Program of Science Technology and Innovation at the John F. Kennedy School of Government at Harvard University. Gentlemen, we welcome both of you. I hope I didn't do too much injustice to your names. I hope I pronounced them correctly. If I didn't, I hope you will correct me. And Dr. Kilama, we would be pleased to begin with you.

STATEMENT OF JOHN KILAMA, PRESIDENT, GLOBAL BIOSCIENCE DEVELOPMENT INSTITUTE, WILMINGTON, DE

Mr. KILAMA. Thank you, Chairman Goodlatte, and Ranking Member Stenholm, and other members of the committee. Actually, you did wonderful. You got my name right on the money. Since this is my first time to be in front of you here, I would like to take a minute to get to know me. I am Dr. John Kilama. I was born in Uganda and now a citizen of the United States. After my education, which included a chemistry degree from Berea College, Berea, KY, and a pharmacy degree from the University of Kentucky in Lexington, and a Ph.D. in Medicinal Chemistry from the University of Arizona, I spent 10 years at DuPont Agricultural Division developing new crop protection products.

I am now the head of Global Bioscience Development Institute located in Wilmington, Delaware. Our goal at the Institute is to support leaders of developing nations overcome apprehension so that they can acquire a sense of ownership regarding biotechnology. Over the past 2 years, we conducted five African regional training courses on biotechnology and intellectual property, 39 Sub-Saharan African countries and five or more leaders did this training. Many of the participants came from public and private sectors. My comments today draw from the experiences of designing and organizing these courses.

I am very happy to be here, Mr. Chairman, excited about this hearing that you are having, and I want to applaud your efforts

today as to determine the extent and impact of artificial barriers to trade and food aid in agricultural products produced through biotechnology. My testimony today will focus mostly on Africa, although I will, if time permits, say a few words about China and India, two countries obviously of great importance for trade matters. I ask at this moment that my full testimony be submitted for the record.

There is widespread apprehension of biotechnology in Africa and other developing countries. No new story dramatizes the challenges confronting the biotechnology sector more dramatically than the refusal by Zambia and other southern African countries to accept American food aid processed from genetically modified crops last October. I believe there are four major reasons, in my opinion, so many Africans are having difficulties in adopting biotechnology. Those reasons are some of those already been alluded to by you and others.

First, the Africans have close ties to Europe's economic market. Africa's close economic ties with Europe are making it very difficult for the African government to embrace biotechnology. Africans are very worried that European will retaliate against African exports if Africa accepts GMO's. For example, from 1999 to the year 2000, Zambia exported more than 8,400 tons of produce to Europe, earning about $62.6 million. Let me quote to you what the vice president of Zambia, Mr. Enoch Kavindele, said to some of the UN workers. "Our decision to reject some of these foods is out of fear. We have been told that we lose our European market if we start growing GM foods. Hungry we may be, but GM foods pose a serious threat to our agriculture sector and could grind it to a halt." Mr. Chairman, this is what Africans are facing with regard to trade and biotechnology.

The second reason, which I feel if very important, is Africa's inability to create biosafety laws affected by technology policy that is creating limited private sector development in Africa. Even if the European issue wasn't there, Africa would still be having problems adopting biotechnology because of the inability of African governments to develop a coherent strategic policy for enacting and implementing biosafety laws. To date, and somebody can correct me, I am not aware of any single country in Sub-Saharan Africa that has enacted any laws for enforcing biosafety regulations. And that means the lack of regulatory, means that companies that want to import and sell GM seed will not be able to do it. Applications to field test transgenic materials developed locally or from international sources are not possible. Approval for importation of GMO's as commodities or for research and testing purposes are delayed. There is no mechanism to process requests for authorization to produce or to grow GMO's on a large scale for commercial purposes. In some cases, even the movement of GMO's within these countries is very much restricted.

So why aren't African governments acting decisively to create biosafety laws? This brings me to the third reason, which is the capacity crisis within the African government institutions. In my discussions with many African leaders, I have determined that the lack of appropriate human capacity is a major obstacle. Most officials and the ministries responsible for enacting biosafety laws lack

the policymaking skills required for drafting coherent, consistent and effective legislation, and pushing those drafts through the legislative process. To me, this is the crisis that has resulted from reduction of development assistance provided toward nurturing the growth of leadership in African government ministries.

Lately, many of the donors have shifted their approach to working directly with local communities rather than work with key government ministries. I have no quarrel with anyone that is working directly with local communities, but I feel strongly that this approach should not come at the expense of neglecting government institutions. In addition, this assistance is normally not clearly coordinated to target specific needs of the countries that receive it. The result has been a significant shortage of people in government who have the skills to develop strategy and policy in areas like biotechnology.

Mr. Chairman, foreign assistance to Africa should be carefully thought out so that it focuses on producing long-term benefits, not short-term emotional satisfaction. The first leaders must be supported from the public and private sectors, from local communities to key national ministries that include ministries like Health, Agriculture, Environment, Trade, Justice, Science and Technology. Otherwise, we risk an incomplete consensus and resentment among at least some stakeholders.

I also strongly believe that these countries must be required to put on the table a certain percentage of the project. They should also be brought in full partnership from the onset of any developmental assistance. No matter how corrupt and mismanaged African government ministries may be, we must figure out a way to train government officials in the key leadership skills of policymaking and implementation.

I would like to draw your attention to the current Secretary General of United Nations, Kofi Annan. He was one of those groups of people in the 1960's that were trained by support from international groups that wanted to provide a lot of key people that would gain experience in policy decisions.

I would also like to draw your attention a little bit of to Botswana, the southern African nation that now has the highest per capita foreign exchange reserves in the world. The secret of Botswana's economic growth isn't the country's great mineral wealth. After all, many African countries have enormous mineral wealth. The key to Botswana's success is that Botswana has successfully nurtured the policymaking and implementation skills of a broad range of leaders in both the public and the private sector. So it might be wise for some of this assistance to provide opportunities for some of the Africans to actually go to Botswana and see the kind of things that the government are doing in terms of providing leadership within the country.

And the last reason has to do with this unprecedented barrage of negative publicity about biotechnology by extremist groups. These groups have labeled GMOs and the products made from them as seeds of inequity and ruin. Because of inadequate counterbalance to these extreme groups, it is not surprising that some African governments are swayed by these crazy rumors.

And so let me just conclude by talking a little bit about China and India. Of the last 6 months, I spent more than 3 weeks in China, first on a trade mission with the city of Philadelphia, and second, on invitation from Anhui Province. It happened to be the province from where the current Premier of China comes from. And I really have come to a conclusion that China has embraced biotechnology. Unfortunately, in the last few weeks or so, we have seen that the central government is dragging their feet in terms of allowing trade to occur, and this might simply be because China feels very strongly that they need to upgrade their biotech companies to be able to compete with international product.

On the other hand, in India, my visit to Karnataka State in Bangalore has indicated to me that there is a tremendous interest in biotechnology as witnessed by approval of Bt cotton, which is now in use in India. And there is an enormous amount of biotech activity in the state and other states in India, which indicates that they have recognized the importance of biotechnology for their economic development.

So in summary, if you may permit me, first, I feel strongly that biotech can have a bright future in Africa. How bright will depend on how effectively leadership in Africa acquires the skills it needs to create effective, coherent policy and build support for it among all stakeholders.

I also feel that it is very important that we recognize some of the success that has taken place with support from USAID. A kind of example I would like to emphasize, USAID together with Monsanto provided support to Kenya Agriculture Research Institute and AGERI in Egypt. And the result has been that these institutions have provided a foundation upon which the country can draw a lot of expertise, and these are the kinds of experiences that I would like to bring up to your table. Thank you very much.

[The prepared statement of Mr. Kilama appears at the conclusion of the hearing.]

The CHAIRMAN. Thank you very much. Let me remind all of the witnesses that their entire statements will be made a part of the record and that they will be very helpful to us if they would limit their comments to 5 minutes. And at this time, we are pleased to welcome Dr. Juma.

STATEMENT OF CALESTOUS JUMA, DIRECTOR, PROGRAM FOR SCIENCE TECHNOLOGY AND INNOVATION, JOHN F. KENNEDY SCHOOL OF GOVERNMENT, HARVARD UNIVERSITY, CAMBRIDGE, MA

Mr. JUMA. Thank you, Mr. Chairman. I am very pleased to have this opportunity to be here, and I promise you that I will keep within the time limit.

I am currently professor of the Practice of International Development at the Kennedy School of Government at Harvard University. Before going to Harvard, I was the executive secretary of the United Nations Convention on Biological Diversity under which the Biosafety Protocol that regulates trade in genetically modified products was negotiated. And so a part of my testimony this morning derives from my experiences as executive secretary of the Convention, but also, more recently, as well as from my own research in

terms of being able to look back and see what the negotiations implied both for international trade and also for the developing countries.

I have come to the conclusion after looking back and conducting research over the last 4 years, that the regulatory uncertainty that prevails in the international arena at the moment has significant implications for the developing countries at least in three areas: First, in the area of the ability of the developing countries to meet their basic needs; second, their capacity to participate in the global economy through the improvement of the agricultural products; and third, through possible disruptions in international partnerships arising from objections to the use of genetically modified products.

This is particularly interesting because since a decade ago most of these countries have, in fact, signed onto a large number of international commitments where they recognize the importance of biotechnology. And many of them, in fact, put in place policies and programs that were aimed at developing their own capacity to participate in the biotechnology field. What subsequently changed was a shift in the legislative authority on biotechnology away from ministries of agriculture to ministries of environment. As a result, much of the negotiation that has taken place over the regulation of agriculture products has been led by institutions that are not responsible for agriculture production. And this, generally, has had a negative impact on the ability of those with the locus standi to, pronounce on agricultural issues. They have become marginal to many of the major international negotiations. And so the regulatory atmosphere to a large extent has been hostile to the development of new technologies.

I have, during my own research, documented at least three areas of impact on the developing countries arising from this uncertainty in the regulatory system globally. One is the impact on domestic research in the developing countries themselves, and this is arising from the fact that these countries are very concerned about investing resources in biotechnology without knowing whether they will have access to international markets. Second, they are concerned about about the ability of the international community to rally resources to support biotechnology in such developing countries; especially, where there are major differences between the United States and Europe. And third, an issue that has been raised already, which relates to a capacity of these countries to participate in trade, particularly, using genetically modified products.

A related question that is linked to the impact on humanitarian activities which my colleague has already referred to.

I would like to conclude by proposing at least three areas that I believe require urgent attention. The first is being able to establish a certain degree of certainty in the global regulatory arena, whether it is done through adjustments in existing practices, regulatory practices, or through arbitration, whichever the case might be, but I think it is essential to stabilize and bring a certain degree of predictability in the international arena. Second, I believe there is an urgent need for the developing countries to enter into long-term biotechnology research partnerships industrialized countries. A large part of the objection to biotech is arising from the fact that

many of the African countries are not yet stakeholders in the technology itself. And finally, I think it is essential to strengthen the science and technology policy capability of the developing countries so that decisions on biotechnology are taken in the context of science and technology and not in the context of other institutions, especially, in this respect to environmental institutions.

I want to thank you again for giving me the opportunity to appear before you.

[The prepared statement of Mr. Juma appears at the conclusion of the hearing.]

The CHAIRMAN. Dr. Juma, thank you, and Dr. Kilama, thank you for your very helpful comments, both of you. We will come back for some questions in a moment, but first, we have been joined at the witness table by Congressman Frank Wolf. Congressman Wolf has been a leader in the Congress for a long time on humanitarian issues. He is somebody for whom I have great respect and who I know has been to many of these countries has seen the need and who was amongst those who urged us to bring this issue to the floor. So Congressman, we will thank you for that, and thank you for joining us today, and we would be pleased to hear your testimony.

STATEMENT OF HON. FRANK WOLF, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF VIRGINIA

Mr. WOLF. Thank you, Mr. Chairman. I appreciate your holding this hearing, and I had the opportunity at the request of our former colleague, Bill Emerson, who has since passed away, and Congressman Tony Hall, who is now at the United Nations, to get active in this issue. We all went to Africa in 1984 in the famine, and I had the opportunity to visit Ethiopia and Eritrea again in January of this year.

There are over 30 million Africans whose lives are in peril as they struggle for their next meal. We saw women and children that were too weak to feed themselves, and it is absolutely tragic that in a world with food as plentiful as ours, that we are now going through famine of what I would call biblical proportions.

I would like to take a few minutes and show you why I am here today. The barriers our agricultural products face when providing humanitarian relief is affecting real people, starving people, around the globe. If we could just show 2½ minutes of the tape.? This was in a village not very far from Addis Ababa; 11.5 million people are at risk of dying, 3 million are ready to be added to the list, 1.5 in Eritrea. She was 5 years old. These children couldn't stand up.

Thankfully, Mr. Chairman, those scenes were not of Zambia or India, but it could have just as easily been. Last year, the Zambians turned down the offer of genetically modified maize from the United States, saying the safety of the food had not been proven. It also declined the offer of a milled version free from seeds that farmers could plant. I have submitted for the record an article from the paper there, the National Post, that said Lusaka, about 6,000 hungry Zambian villagers in this village 3,300 kilometers from the capitol, overpowered an armed policeman and looted 230 tons of food aid, mostly corn, rejected by the government because it was genetically modified. Police said yesterday, despite the

threat of starvation facing more than 2 million people, Zambia has banned all GM food.

[The article from the January 29, 2003 National Post follows:]

LUSAKA—About 6,000 Hungry Zambian villagers in Sizanongew, 300 kilometers from the capital, overpowered an armed policeman and looted 230 tonnes of food aid, mostly corn rejected by the government because it was genetically modified, police said yesterday. Despite the threat of starvation facing more than 2 million people, Zambia has banned all GM food.

Mr. WOLF. This is really a trade issue, but more importantly, it is an issue of life and death. There are countless numbers of women and children whose life could be needlessly cut short if this thinking continues.

American agricultural products are among the safest in the world. Even Europe officials admit the EU policy to put pressure on African governments to reject food aid containing genetically modified organisms. This is tragic, because genetically modified crops boost yields and could make Africa less dependent on foreign food aid. Developing countries are hampered in their efforts to use biotechnology and to engineer and improve crops because modified produce is not acceptable to European markets.

In India, for instance, officials have always maintained European style safety concerns about genetically modified food. Last November, authorities demanded a written guarantee that aid shipments from the United States contain no GM grains whatsoever. Relief workers in CARE, which is a great organization, and Catholic Relief Services, could not comply. After 6 months of stalemate, when people were hungry, they had the sacks of flour shipped off to Africa. And in the meantime, India has allowed no new shipments of U.S. corn-soya flour, and that is tragic. Boatloads of flour waiting to be consumed by hungry people in India. Thankfully, hungry people in Africa were able to use it, but what about the women and children in India?

This is a global crisis demanding a global response. No one country can meet the needs in Africa and around the world. In the year 2000, the United States, our Government, our taxpayers, have contributed 51 percent of all the food feeding the hungry people, and that is great, that is appropriate, that is good. That shows the compassion that we are. If you look at the European Commission, Europe's combined contribution is 27 percent of the donations to the UN World Food Program. They have more people in all of Europe, but they have only given 27 percent. We have fewer people and we have given 51 percent. EU countries like France have the ability to contribute more, but instead of responding to this international crisis, the situation is being made worse by the EU's opposition to importing biotech agricultural products. Should these African countries recover their agricultural industry, they would then not be able to sell their products to their main export; that is Europe.

In closing, Mr. Chairman, irrational fears has replaced moral compassion for hungry mouths around the world. People are afraid of foreign genes somehow contaminating their own crops and fields, and they are afraid their farmers might grow dependent on the U.S. companies for GM seeds. I hope and pray that fear will be overcome quickly. And I might say, Congressman Tony Hall, that is one of Tony's main jobs that he is doing is promoting this and

answering these unfounded charges that are being made by some. Regular droughts have exacerbated the current famine in Africa and the rest of the world. With more drought resistant crops, many of these countries could become self sufficient rather than merely struggling to survive one year later. I really think this is an issue, obviously, of trade, but more one of life and death. Thank you, Mr. Chairman, for holding the hearing.

[The prepared statements of Mr. Wolf and Mrs. Emerson follow:]

STATEMENT OF HON. FRANK WOLF, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF VIRGINIA

Mr. Chairman, thank you for allowing me to testify today before this distinguished committee. As many of you know, I have traveled to Africa to witness the devastation of famines, first in 1984 and most recently, earlier this year.

There are 30 million Africans' lives in peril as they struggle for their next meal. I saw women and children that are too weak to feed themselves. This is absolutely tragic in a world with food as plentiful as ours.

I'd like to take just a few minutes and show you why I am here today. The barriers our agricultural products face when providing humanitarian relief is affecting real people, starving people around the globe.

Thankfully, those weren't scenes of Zambia or India, but it could just as easily have been. Last year, Zambians turned down the offer of genetically modified maize from the United States, saying the safety of the food had not been proven. It also declined the offer of a milled version free from seeds that farmers could plant.

This is a life and death issue. There are countless numbers of women and children whose lives could needlessly be cut short if this thinking continues. American agricultural products are among the safest in the world—even Europe's officials admit that.

EU policies put pressure on African governments to reject food aid containing genetically modified organisms. This is tragic because genetically modified crops boost yields and could make Africa less dependent on foreign food aid. Developing countries are hampered in their efforts to use biotechnology to engineer improved crops because modified produce is not acceptable to European markets. (The major export market for most of these countries).

In India, for instance, officials have always maintained European-style safety concerns about genetically modified foods. Last November, authorities demanded a written guarantee that aid shipments from the United States contained no GM grains whatsoever. Relief workers at CARE and Catholic Relief Services couldn't comply. After 6 months of stalemate, they had the sacks of flour shipped off to Africa. In the meantime, India has allowed no new shipments of U.S. corn-soya flour.

Isn't that tragic? Boatloads of flour waiting to be consumed by hungry people in India. Thankfully, hungry people in Africa were able to use it, but what about the women and children in India?

Irrational fear has replaced moral compassion for hungry mouths around the world. People are afraid of foreign genes somehow contaminating their own crops and fields, and they're afraid their farmers might grow dependent on U.S. companies for GM seeds.

I hope and pray that this fear will be overcome quickly. Since 1984, Africa has suffered regular droughts which have exacerbated the current famine situation in Ethiopia and Eritrea today. With more drought resistant crops, these countries could become self-sufficient rather that merely struggling to survive one year to the next. Don't these nations owe that to their hungry women and children?

STATEMENT OF HON. JO ANN EMERSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

I currently serve as a co-chair of the Congressional Hunger Center. This bipartisan, non-profit organization will reach its 10-year anniversary this year. Its success in educating leaders to fight hunger comes in part from its connection to the former House Select Committee on Hunger. Founded in 1983 by Congressmen Benjamin Gilman, Mickey Leland and Tony Hall, the Select Committee on Hunger was known for its efforts to find real solutions to national hunger and poverty. Congressman Mickey Leland chaired the committee until he lost his life during a humanitarian mission to Ethiopia in 1989. Congressman Leland felt strongly that hunger could be ended and lamented, "I cannot get used to hunger and desperate poverty in our

plentiful land. There is no reason for it, there is no excuse for it, and it is time that we as a nation put an end to it."

Congressman Tony Hall succeeded Congressman Leland as chairman of the Select Committee on Hunger until the House of Representatives voted to eliminate all of its select committees in 1993. Congressman Hall responded by embarking on a 22-day fast, an act that helped bring Republicans and Democrats together to create the Congressional Hunger Center. In 1994, my late husband, Bill Emerson joined Tony Hall as the first co-chair of the bipartisan Congressional Hunger Center.

For over 50 years, the U.S. Government and the American people have provided food assistance to foreign countries. Immediately after World War II, commodities stockpiled for the U.S. military were made available to the people of war torn Europe and Asia through private voluntary organizations. As part of the Agricultural Act of 1949, the Secretary of Agriculture was granted authority to donate or sell surplus U.S. commodities abroad. This was used until the mid–1950's and then reactivated in the early 1980's in order to reduce the stockpiles of surplus commodities that the USDA Commodity Credit Corporation had accumulated. Our food aid efforts have expanded in recent years but we have the capacity to do so much more. I hope that in my involvement with the Congressional Hunger Center, I am able to follow in the footsteps of my predecessors and eliminate hunger and poverty for our Nation and for the world.

In the world today, there are 800 million hungry, malnourished people who need food now. America's farmers harvest a bounty big enough to feed America, export around the world, and share with the hungry in developing countries. We are very fortunate and empathetic to the plight of those who do not share our good fortune. Americans are in the position to help and we want to share the bounty of our harvests. Our food is safe, nutritious and available now.

Our farmers are among the most productive on Earth, using the best technologies available for conserving resources, protecting the soil, and preserving the environment. They continue to improve year after year with better products and practices. Our food provides one of the safest, most nutritious and most diverse diets ever enjoyed by people anywhere, and we continue to improve on these qualities as well.

The most effective way for us to share our bounty is to share our food directly and not sending our tax dollars to buy food from farmers in some other country. We lead the world in sharing access to our educational system, our technology and know-how, and the skill of our farmers with developing countries so that they can better learn to grow food themselves. The equation is simple: there is safe and nutritious food available now and there are people who are hungry now. There is only one moral solution to this equation. There is ample time and means for each country to make long-term choices about food and technology policy without letting people go hungry or putting them at risk.

Our technology has allowed us to make great strides in the realm of biotechnology. Biotech helps American farmers grow more and better food, saves our resources and protects our environment with economic benefits for growers. Biotech can also help African farmers develop a more productive, nutritious and profitable agriculture in Africa - helping reduce hunger, poverty and environmental harm. The governments of several countries in southern Africa have expressed concern about receiving grain, specifically maize, that may include biotech traits in commercial use in the United States, as food aid to help address famine.

Africa is on the verge of catastrophe. The causes are many but the most pressing are the HIV/AIDS epidemic and drought. Six million Ethiopians are in need of food. In southern Africa, U.S. and international experts agree that the worsening food crisis places as many as 14.5 million people at risk. These people do not have food today. Zimbabwe is heading for disaster and the situation in Zambia may be even worse.

African governments' concerns about accepting food aid containing biotech traits arise from their lack of national biosafety assessment and regulatory capacity, as well as concern over potential trade issues with the European Union. In addition, other countries have proposed to impose onerous segregation and labeling requirements on imports of biotech crops and active anti-biotech activism is raising unfounded concerns. To date, the governments of Mozambique, Malawi, Swaziland and Lesotho have agreed to accept biotech grains as long as they are milled, which will prevent them from being planted as crops. The Zambian government has agreed to use the milled grain only to feed the country's refugees but the grain will not be distributed to the general population.

The situation in Zambia best illustrates the problem that we are facing. In Zambia, 3 million people face the possibility of starvation because of drought. Relief maize was being sent to the area. The government discovered that it was partly GM and believed that accepting it had major environmental and perhaps health implica-

tions. Lacking the laboratories and protocols, Zambia turned to Europe for guidance and rejected 63,000 tons of our maize. This situation shines light on just how much influence Europe has on the situation.

Some governments are actively blocking the delivery of emergency food relief needed to head off starvation. Their excuses stem from the ongoing debate over biotechnology, spurred in part by the bias against biotechnology of certain European lobby and interest groups. As a result, food that should have been going to these countries is not getting there. Meanwhile, the debate rages inside those countries over the human health and environmental risks posed by the corn that millions of Americans eat daily. It does not take a lot to calculate the impact of these arguments by well fed experts. As the region heads for famine, vulnerable people will perish.

While we respect the rights of countries to make their own decisions about biotech, other donors have not stepped up to fill the gap if US food aid is turned away. The United States provides two-thirds of the food aid needed to meet emergencies around the world. All this food comes from our stocks and markets. It is the same food we eat. All of it has passed our own food safety and environmental impact testing—the most rigorous in the world. For this reason, U.S. biotech and non-biotech foods are mixed together. There is no need to separate them.

I am concerned that Europes' attitudes toward biotech are profoundly shaping the African response. The moratorium in Europe is contributing to fear, confusion and misinformation about the safety and benefits of biotech in agriculture, leading to a profound chilling effect on developing countries who most need the benefits of this and other new technologies. This is reflected in apprehensions about eating the same food we eat here in the United States, and contributes to holding up the application of biotech to serious problems in Africa and other developing regions of the world.

The bottom line is quite simple: the food and grain contained in aid shipments to Africa from the United States contain the same tested and safe foodstuffs grown and consumed daily by 285 million American citizens. Biotech crops and ingredients undergo rigorous safety testing and regulatory assessments. No other food crops in history have been tested and regulated as thoroughly as foods developed through biotechnology. Food aid containing biotech traits meet the safety assessment processes established by the World Health Organization, the Food and Agricultural Organization, the Codex Alimentarius Commission, and the Organization for Economic Cooperation and Development. These safety assessment processes establish substantial equivalence to ensure that biotech foods are at least as safe as food produced from conventionally bred crops.

Food aid is a complement to development and trade— malnourished people can't wait for development and underdeveloped economies have little to trade. America is helping on all three levels: food now for the hungry, development assistance for farmers and capacity building, and working towards a level playing field for fair and open trade to benefit all countries.

Effective tools are available to growers who want to cater to specific agricultural markets and regions. Food aid, agricultural development and export markets can coexist with cooperation and compatible, reasonable standards. The ample evidence of the safety of biotech crops—both human and environmental—should reassure countries who have not yet developed full regulatory processes on biotech food that they are not endangering their people by granting temporary allowances of the biotech traits for humanitarians needs. Countries do not need to make a choice between their long term sovereignty and their short term needs.

The CHAIRMAN. Thank you, Congressman Wolf. We are going to proceed with questions now. If you would like to remain, you are welcome to do so.

Mr. WOLF. I am chairing another hearing, and if I could be excused, I would do that.

The CHAIRMAN. Absolutely. We certainly appreciate your contribution today and thank you, again.

Mr. WOLF. I thank the chairman and I thank the members.

The CHAIRMAN. Dr. Kilama, can you tell us more about your training sessions with African policy leaders in the Global Bioscience Development Institute? I am intrigued that you are able to have participants from so many countries. I understand almost 40,

including Zambia, participated, and we would love to know more about the progress you feel you are making in that regard.

Mr. KILAMA. Absolutely, Mr. Chairman. When I left DuPont, one of the things that I recognized was that there is a tremendous gap, especially, in Africa, in terms of really understanding some of the international issues, as well as regional and local issues. In terms of looking at policy as a vehicle for promoting development, we then design a course in which we bring in different groups of people from a specific region, and we kind of tailored it, the regional approach, based on what is already existing. For example, like the SADC, the Southern African Development Community or the ECORS, and bring a diverse group of people to begin to understand the issues that, for example, pertain to the bio-resources that they have an enormous amount of it, and how they can translate that availability of bio-resource into economic development. And also, look at the issues of intellectual property, which is very important, because I believe that ingenuity within each community exists, and one way to promote it is to embrace the protection of that ingenuity, and then look at different technologies that are available which can support a lot of this economic development.

And so we have brought in a diverse group of people consisting of lawyers, consisting of scientists, consisting of managers and policymakers in private sector together in this training. At the same time, we also bring very diverse people from around the world. In fact, in our training, we normally average between 20 different people from 20 different countries, including the United States, Costa Rica, for example, Chile, Japan, India, the EU, to come and bring different experiences in their country into Africa. We don't bring the people into the United States. Instead, we bring these experts from around the world into Africa, therefore, allowing us to draw in a larger group. And the training lasts for 3 weeks consecutively, Monday through Saturday, from 9:00 a.m. to 6:00 p.m. We carefully select these people, people who we feel are very committed to their country, and to be able to learn and go back and try to make a change in their institution or their country. And we have been able to do that five times. The first was two in East Africa, one in southern Africa, two in West Africa to accommodate the Anglophone and the Francophone.

The CHAIRMAN. Thank you. Dr. Juma, do you think the European Union's anti-biotech attitude in its regulations on labeling and traceability are spreading around the world? There seems to be no scientific justification for the principles that they have articulated. Are the Biosafety Protocol and the precautionary principle which they have put forward responsible for this attitude?

Mr. JUMA. The answer to your first question is yes. Those ideas are being articulated through a number of international instruments, one of them being the Biosafety Protocol which now has 45 ratifications. It will come into force on the 50th ratification, in which case it becomes international law. That would be, basically, the first major establishment of the precautionary principle in international law, and I think that that is going to happen pretty soon. It is going to be a major step in terms of consolidating the position of the European Union in terms of being able to argue that

their principles regarding regulation of safety of food are being accepted worldwide, so I think that is an important development.

My own personal position has always been that it would have been better for the United States to have been a party to the Conventional on Biological Diversity under which the Biosafety Protocol was negotiated. The United States would have used the opportunity of being a party to argue its case strongly. Second, the same ideas are being, in fact, proposed in other international regulations. For example, attempts to introduce the same principles in the Codex Alimentarius.

So the answer to your question is yes, and I think that it is going to not only affect genetically modified foods, but these principles, when they become international law, will be extended to other areas which do not include genetically modified foods.

The CHAIRMAN. It is very concerning to me. What are the consequences in terms of feeding people in Africa and other parts of the world if that next step were to occur?

Mr. JUMA. My personal opinion on this is that we are basically at the point of divergence, that we have really two systems. And the African countries, in particular, will not make choices in favor of biotech unless they see that they have, in fact, a stake in it. So my argument is that the United States needs to be active in forging biotechnology partnerships with the African countries. And as soon as they become stakeholders in the technology, they can take a stand. Right now, they cannot take a stand because they are not stakeholders in the technology. They are being asked to accept products of biotechnology. My argument is that they should be part of the acceptance of the product, but also the development of the technology itself.

The CHAIRMAN. Thank you very much. The gentleman from Texas, Mr. Stenholm.

Mr. STENHOLM. Thank you, Mr. Chairman. I thank both of you for your very excellent testimony today. The word "moral" is used and abused quite often. But when you think in terms of what Congressman Wolf spoke about a moment ago with 800 million people in the world needing more food every day, I think it is amoral for the developing countries to deny those people the opportunity to feed themselves. Only technology can bring them that opportunity.

And I appreciate your emphasis on the need for education of the leaders; and specifically, I am talking about Africa, but you can say the same of developing countries all over the world, in which the leaders are the problem many times because of the lack of an overt action on the part of developing countries like the United States who have the technology and are perfectly willing to share it, the technology and the information necessary so that leaders can make rational decisions on their own.

I found it very disturbing, Dr. Kilama, in your testimony, that you say one of the reasons why Africa refuses to accept our biologically improved GMO modified foods is fear of retaliation from the European countries. Did I understand and read that correctly?

Mr. KILAMA. Yes. And let me give you one example. Botswana is a major exporter of beef to Europe, and when I was there, I had a chance to talk with President Mogae of Botswana, and one of the things he expressed was that, look, we can't commit suicide here,

because if we decide to bring in biotechnology into Botswana, the first casualty would be our export of beef would simply not be there. And this is the reality. And I think the fact that Europe is a bigger chunk of market for Africa, the issue of biotechnology, in my opinion, has to go through Europe. And no matter how much we try to do, I don't think the leaders in Africa are going to embrace it until the Europeans embrace it, because the fact of the matter is, that is their bread and butter in terms of income. And one alternative, of course, would be to see that the market is opened up in the United States for the African produce, and that may be another way to undercut this stranglehold on the Africans by the Europeans.

Mr. STENHOLM. We have many tools available to work on this education you are talking about, but we also have the WTO process, and right now we have a codex task force on biotechnology which is on the verge of issuing new guidelines on the food safety aspects of biotechnology. Throughout the WTO dispute resolution process, individual countries are expected to look at the codex standards on questions of food safety regulations. What effect do the both of you believe this new codex task force and guidelines will have on this question, if any?

Mr. KILAMA. My short answer to that is that I really do not see, no matter how much regulatory treaties are enacted, until we address the issue of markets, most of this probably will be on paper. I may be wrong. The only major source of income beside minerals in Africa, really, are the agricultural produce. And if they feel that they cannot access this particular market, yes, we can not have the biosafety regulatory in place. In fact, some of them have drafts. Nigeria has a draft; Kenya has a draft which they are working with. Egypt has a draft, but really, to get to the point where there is actual trade in biotechnology in the continent, I don't really see it even if you have the WTO provisions or the Alimentarius. It still is not going to really make a difference in terms of meaningful trade. And so we have to address that particular issue, and to add to that, the fact that there is a tremendous deficiency in terms of understanding the broader picture of biotechnology by the African leadership, it is a major problem.

Mr. JUMA. Codex is the most authoritative international standard on food safety and, therefore, any ideas that get adopted by codex would become, in fact, the international standard. And since WTO uses codex as a basis for decision making, it is important to be sure that codex is, in fact, continues to be a science-based instrument for decision making. My answer to your question is that codex will have an impact on how countries formulate their food safety laws.

Mr. STENHOLM. Thank you very much for your answers.

The CHAIRMAN. Thank you, Mr. Stenholm. I am going to recognize the gentleman from South Dakota in a moment, but I want to just make a comment following on what the gentleman from Texas just said and Dr. Kilama's observation about what is going on in Botswana. I recently met with the Spanish agricultural minister. We actually have some friends in the European Union. The irony is the Spanish grow about—I don't know exactly how many acres, but close to 100,000 acres of GM corn in Spain that they feed

to livestock and sell the meat from all over Europe. You might share that with your friends in Africa. There is a precedent already established for not fearing the consequences of this and that there are those in Europe who are afraid that the backsliding that is going on could actually hurt some Europeans.

At this time, I would like to recognize the gentleman from South Dakota.

Mr. JANKLOW. Thank you, Mr. Chairman. Thank you very much.

Dr. Kilama and Dr. Juma, both of you, I think you both realize we are not dealing with science, and neither are the Europeans or the folks in Africa. What we are dealing with is politics in the most fundamental sense. People are utilizing science, but more than that, they are utilizing the fear of human beings about the unknown, and we all have certain fears about the unknown. These fears about the unknown are utilized to enhance one's economic and political position. Recognizing that and recognizing that all of the scientific studies in the world aren't going to make any difference to the European position, because there isn't anymore you can do. The greatest example of a test project has been the number of years that the people of this country have been consuming these products, a couple of decades.

Way back in ancient Egypt, when a farmer figured out that you could cross two seeds and come up with a better one, when people cut the limbs off of trees and grafted them on other trees, the hybrid corns that we have had for decades, are all examples of what farmers have been doing as long as they have been farming. Now, recognizing all of that, what do you think we can do in the political sense to turn the corner, because we can waste time forever talking about science, but the reality is how do we bring a political solution to a political problem?

Mr. KILAMA. Congressman, I am really glad you have brought the real issue up front, and I fully agree with you. The science is long gone. I think everybody, if they are leaving this world, knows that GMO is not an unsafe product, and so it is a political issue. And that is why I am trying to emphasize that there is a vacuum in Africa in terms of, really, people who would have the leadership skills and political skills to be able to get their political and their people in the country to understand that, and that is why I keep on emphasizing that any support that would provide to Africa—I don't have any problem with short term. I think humanitarian issues and all those need to be done, but the long term really is to be able to support a lot of these educated people in Africa to be able to understand the political skills—I mean, to have the political skills and leadership skills.

Mr. JANKLOW. But aren't we talking about decades for that kind of——

Mr. KILAMA. No, I don't think it is a decade. I think if the process had been going and not interrupted from the 1960's, we would probably not be facing these kind of problems. When Africa was getting independent, there was a concerted effort by many countries, rich countries that is, to support leadership development, and we know some of the people are learning the fruits of that kind of process. But we kind of have moved away from it. Many donors have really moved away from looking at key issues within the gov-

ernment as an impediment to a lot of the problems that we are facing today. And I think we need to begin to redirect our attention to that vacuum which is——

Mr. JANKLOW. Could you make a list of those for us, these types of things that you think we could utilize to redirect our——

Mr. KILAMA. I think when we begin to direct, for example, any kind of assistance, the component of that assistance has to be training the leadership or people in the ministries to understand what the project is and how they can participate fully. If you look at a lot of the problems in Africa today, they are directed to the—in fact, I have talked with many people that support development. They simply say, we can't talk to the government because they are corrupt, they are not going to be effective, and they go directly to local communities. Local communities don't make policy and you still have to be able to work with the government, that you provide——

Mr. JANKLOW. One more quick question, sir, if I could. The Europeans have filed WTO violations against the United States, the WTO has ruled against us. This country at this point in time has not chosen to comply with the WTO's orders with respect—no matter how we feel politically, they have chosen not to comply with the WTO's decision with respect to the European complaints that were apparently proven. What good does it do, and I think we should file, but what good does it do for us to file against them if they are going to ignore the WTO decision like we are doing?

Mr. KILAMA. Maybe Dr. Juma can address that, but my attitude is that, to be honest with you, I am not so sure whether filing a grievance with WTO on biotech is really going to be helpful, because you have got to be able to get the people willing and the political leadership in the country willing to adopt this biotechnology and to adopt this GMO trade. Yes, we may win, but you still have to trade this and people still have to buy it. And if they are resistant within a particular region, I think it would be difficult. Rather than do that, I think we should try to double our efforts in trying to really work closely with many of these people that are opposed at the political level to try to see if we can convince them and not use science as the reason why we want to have biotechnology, because that to me is, as you said, is no longer an issue, and it is the political issue, and we have to figure out skillful ways to be able to convince political leaders.

Mr. JANKLOW. Thank you. My time has expired. Thank you, sir.

The CHAIRMAN. I thank the gentleman. I am pleased to recognize the gentleman from Hawaii, Mr. Case, and I was glad to be able to cite an example from your State in my opening remarks with the use of biotechnology.

Mr. CASE. Thank you, Mr. Chairman, and I wanted to thank you for that example. That is certainly a perfect example of the benefits that can occur. And I can assure you that the papaya industry in Hawaii was very happy with the use of that technology to, basically, save an industry, a whole industry, as a result of the use of technology to develop a resistance in that one strain. And I am also real proud that my home state has long been engaging in biotechnology.

It really is one of the centers in the world for, particularly, tropical and subtropical crops through the University of Hawaii College of Tropical Agriculture. Certainly, through the private sector, I think the Chair cited a couple of decades. I think we have been doing it for, actually, more than a couple of decades in Hawaii and elsewhere in areas such as sugar and pineapple to really yield very high productivity. And I was sorry that the Speaker had left because I was going to note that in recent years, the corn seed industry has done a fair bit of biotechnology in Hawaii because it allows for year-round research, and I am sure that some of the crops in his particular district may have benefited from that research. So I am happy to cross that bridge as well.

Dr. Kilama, I was struck by the same exact point that Mr. Stenholm was when you started to get onto the subject of retaliation in the EU as a result of the use by, or the potential use by, African companies of GMO products. I guess I just want to kind of connect that dot a little bit more, because other members have gone off on the same direction as well. It is one thing for us to have a disagreement between the EU and us over whether the EU will accept our product. It is another thing for them to influence the acceptance of our product elsewhere in the world. And the other thing that strikes me is the testimony from my colleague, Mr. Wolf, that that is crossing the line from commercial imports to humanitarian imports, which seems to me to be a really critical differentiation. Do you agree with that, first of all, that in some of the African countries, the resistance to the use of United States products, or because it is genetically modified, it is being objected to by the EU countries even for humanitarian reasons?

Mr. KILAMA. I agree, and just to add that I think there is just a tremendous fear among a lot of people who are in charge of governments in Africa, that if they go that route, they are not sure they will have that access to the market.

Mr. CASE. Do you know whether they have been told by EU countries? Do you have any evidence or do you have any reason to believe that any of the countries of Africa have been told by countries in the EU that even the acceptance of food from the United States for humanitarian reasons would subject them to retaliation against their exports?

Mr. KILAMA. I don't think there is anything written in paper, but I have talked to at least over 30 countries' leadership in Africa, and I just know that imbedded in their thinking, it may not be something which is written in a paper, that there is just tremendous fear. And I quoted, for example, Vice President Enoch Kavindele from Zambia, who clearly states that we are just very fearful of losing this market. And as long as Europe is resistant to GMO, we really can't put our foot at the door without really knowing what is going to happen. So it may actually be a lot of fear, it may not have real foundation, but the fact is that that fear is there and is inhibiting the ability to embrace biotechnology much more broadly.

Mr. CASE. Is it impacting exports from Africa to Europe for non-food products? I guess I could almost see the argument from the EU if they are taking—I think you mentioned beef from Botswana. If the GMO modified product was being fed to the beef and then it was being sent to Europe, now, I am sure the science is tentative

on that, but at least it would give you a plausible, defensible, maybe rationalization in EU, but is it directed at exports other than Ag, where there is no connection whatsoever scientifically between GMO imports into Africa and then that same product being turned around sent to Europe. Is it just kind of an across the board implication of a threat for exports, generally, from Africa to the EU?

Mr. KILAMA. I think the fear is probably the one that the vice president said. We feel that if we import this food aid, that it will somehow find its way into the farmer's hand, and they will start growing the GMO, which will then create this problem. So it is not so much the actual food aid is a problem. It is a problem with the possibility of this getting into the agriculture chain in terms of production of other agricultural produce.

Mr. CASE. Okay. But let me just—my time is out, but that is what I am getting at. Is the implication from the EU countries that they will not accept exports of any products from Africa, whether it is agriculture or not if they take imports from the United States that are GMO products?

Mr. KILAMA. No. This is only pertaining to agricultural products.

Mr. CASE. I see. So they are trying, they being the EU, is trying to develop that link of the product around the corner?

Mr. KILAMA. Right. And I refer to the Congressman from South Dakota that it really is political, and I think what Europe is looking at is for whatever reason, whether it is because they feel they are behind the United States in terms of ability to compete with the biotech product, or for whatever reason. It could be, and I am only guessing, others may have a better understanding than I have, to actually stall as much as possible to allow them to be able to get to a stage where they can compete. And we have seen that. I have seen that in China, as well, where there is this precautionary principle being now sort of brought up to the front door as a way to, in my opinion, to stall so that the local private sectors are in a position to compete. I don't see that with Europe, though, because there are a lot of companies like Syngenta, AstraZeneca, that are European-based companies, are very active in biotech. So I don't understand the case of Europe.

Mr. CASE. Okay. Thank you very much.

The CHAIRMAN. I thank the gentleman. The gentleman from Minnesota, Mr. Gutknecht.

Mr. GUTKNECHT. Thank you, Mr. Chairman. I want to thank you for having this hearing and I apologize to all the people that were here because you need to know there are a lot of other meetings going on right now, and that doesn't mean that this issue is not critically important. And I don't see how anyone could watch that 2½-minute video presented by Mr. Wolf and not be moved and not feel just almost visceral anger that political forces are helping to create an environment that allows that kind of thing to happen anywhere on this planet. So I think this committee needs to do all we can to try and stop some of that political nonsense.

I want to also thank my colleague from Hawaii, Mr. Case. I don't know if they were genetically modified, but on the occasion of my birthday last week, the people of Hawaii provided me with some papaya, and if there ever was a sweeter pineapple, I have never

tasted it. It was wonderful. So I don't know if it was GMO or not, but it was wonderful and I want to thank him.

I want to pursue something, too, that was mentioned by my colleague from South Dakota. And perhaps, Mr. Chairman, sometime we ought to have a hearing and invite in some American Indian historians because I don't think even people on this committee realize the contributions that American Indians have made to what some might describe as genetically modified crops. The potato was not bred in Ireland. It actually was bred by American Indians here in the United States of America. The tomato, we all know the story of corn and, obviously, of tobacco, and they played a very important role in cross breeding various plants and coming up with many of the products that we all take for granted today.

So the idea of genetically modified crops is not something that is particularly new. It goes back many centuries, and I think we can play a role in this committee. But at the end of the day, I am not really convinced there is much we can do because one of my concerns, and perhaps you want to respond to this, is that the seed industry today is dominated by a relatively small number of multinational pharmaceutical conglomerates. Many of them are based in Europe. And I would use as an example, a couple of years ago, and without naming specific names unless I have to, one of these large conglomerates owned a very large seed company and they had invested hundreds of millions of dollars developing genetically modified crops and marketing them to our farmers. And at the same time, they owned one of the largest baby food companies in the world. And so on one hand, they were marketing genetically modified seeds to our farmers, telling them that they should grow those, and at the same time, at the very same time, they were saying publicly that for their baby food company, they would not buy them.

Now, it seems to me no matter what we do politically here in the United States, no matter how much pressure we put on the USTR, or the European Union, or whatever, as long as you have CEO's of major conglomerates who are involved in this, who don't have the courage to say what they know to be true, it seems to me that all that we do here in Washington, all that we do in our trade discussions, goes for naught if the leaders of these multinational pharmaceutical companies don't have the courage to say what they know is true. Would you like to comment on that?

Mr. KILAMA. Yes, I could, without getting the trouble. Congressman, I don't have the view that it is really the corporations that are the issue here. I mean, companies are there to make money, and that is their job, and they could do what they have to do in order to sustain their livelihood. That does not prevent any individual or countries to be able to participate at research level and develop their seeds. Besides, in the case of Africa, there are a lot of crops that probably don't have very much economic value to these large corporations you are referring to anyway.

And so, yes, they could come and speak, but on the other end, if they stick out their neck too much and they start losing money, we wouldn't have these corporations available. So I know there is the bashing by a lot of people of the private sector. I don't think that is the issue to me. The issue is are there people who under-

stand that biotech is not just for agriculture, but really is the future for economic development? And that they ought to take a serious look at how they can participate in creating this kind of investment and creating this kind of opportunity; not just to help the agriculture sector but to help a lot of other sectors in times of economic development.

Mr. GUTKNECHT. Mr. Chairman, I will yield back my time, but I want to reserve the right to continue to demonstrate the pernicious nature of some of the large pharmaceutical companies and what they have been doing around the world to American consumers and consumers around the world. I yield back.

The CHAIRMAN. I thank the gentleman. We have a vote coming up, but we have time to get one more individual's question in. We will recognize the gentleman from North Carolina, Mr. Ballance. Welcome.

Mr. BALLANCE. Thank you, Chairman Goodlatte and Ranking Member Stenholm. Very briefly, I recognize this is an important issue in my State of North Carolina, and particularly, in my district where we do a lot of farming. I want to just raise this brief question, Dr. Juma. And we will take it back, to try to stay out of the politics of it, take it back 2 years. Are we doing enough from our executive branch? This is a great meeting and this is a great issue that we are bringing up in the Congress, but at the highest level of our executive, and as I say, go back to the Clinton administration. Are we making head-to-head contacts with governments to the level that we need to on this issue?

Mr. JUMA. The answer is no. And I would submit that there is a need to have a certain degree of executive leadership on this particular issue because the concerns and misinformation are expressed in many countries at the highest level possible in government. We have had presidents of countries making incredible statements, both publicly but also privately. And so I believe that the issue has gone beyond just the general areas of either public education or simply education. I think it will have to involve some high level engagement.

But I think the entry point for this engagement, and I want to come back to the question that was raised earlier in terms of what you could do politically. I think that in my own assessment and my own research, those countries that have a certain level of research capability, however modest, it is in the area of biotechnology, are less likely to embrace a protectionist position because they expect at some stage in the future to become players in the area of biotechnology. So I would argue that the level of engagement at the highest level possible should be in the context of creating biotechnology partnerships and alliances between the United States and the key developing countries. But in the absence of that constituency, a vacuum, a technological vacuum, exists that is being populated by the anti-technology activists. So I would strongly argue that it cannot be empty leadership. It has to be leadership that is tied to actual partnerships in the construction of biotechnology platforms, and that is what I think is going to make a difference.

Mr. BALLANCE. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. The vote on the floor is on the previous question on House Resolution 160, the Child Abduction Prevention Act. I intend to come back and resume questioning after that vote is concluded, but two members cannot return. I am going to recognize them each for 1 minute. The gentleman from Michigan, Mr. Smith, and the gentleman from North Dakota, Mr. Pomeroy. Mr. Smith.

Mr. SMITH. Gentlemen, thank you for being here. I chair the Research Subcommittee on Science and we have held three hearings on biotechnology so far. We are scheduling another hearing specifically on Africa in hopes that if we can do something that is really helpful and really good in biotechnology in some of those countries, it might be something that would expand a lot of impression. So I have asked my Science Committee staff to sort of catch you when we run for a vote, and so Dan Byers is going to be talking to you about either submitting testimony. In our legislation that was passed in December, we said that we are going to provide money to bring in scientists from the African countries to work with American scientists in developing the kind of products that they think would be most helpful in their country. So hopefully, we can get our foot in the door. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. The gentleman from North Dakota.

Mr. POMEROY. Mr. Chairman, thank you for holding this important hearing, and it has been excellent. I want to commend to all paying attention, and in particular, the testimony of Dr. Juma, because I think it is a very well rounded statement about this issue. The issue is far more than whether or not we can get our commodities produced with this technology into Africa. It is about the evolution of the technology itself for application in developing sustainable agriculture in Africa.

It seems to me some of the difficulties we have had with global acceptance of biotechnology has been that we have ignored principle number one, what does the marketplace want. And so our initial efforts have been more at how much pesticide you can put on the commodities we are growing here for improved production efficiencies, not nutrition, flavor, things that the customer is going to call for in looking at the product.

In Africa, and I cite specifically page 6 and 7 of the testimony, today's technological capabilities in fields such as genomics make it possible to adapt crops to these diverse ecosystems in ways that are consistent with the principles of sustainable agriculture, yet, you go on to note developing countries that need biotechnology most are also the ones least involved in its development. Trends show the early diffusion of transgenic crops has been largely in temperate regions and limited to a few major commercial crops. The promise of biotechnology to meet the needs of low income families in developing worlds still remain a distant dream.

You don't point any blame for that, but you do indicate more can be done in this area, and if we want to improve receptivity of Africa as a major potential market area for biotechnology, we need to work on developing sustainable crops that will aid ongoing food sustainability in Africa. I really commend that testimony. I found it very interesting. Mr. Chairman, thank you.

The CHAIRMAN. Thank you. The committee will stand in recess until after this vote. We will start back up as soon as I get back.

[Recess]

The CHAIRMAN. The committee will be in order, and at this time, I will recognize the gentleman from Minnesota for any questions he might have.

Mr. PETERSON. The next panel maybe.

The CHAIRMAN. The gentleman from Kansas.

Mr. MORAN. No questions, Mr. Chairman, thank you.

The CHAIRMAN. Any other questions? Well, gentlemen, it seems like we have detained you unnecessarily. We thank you very much for your participation today. Your contribution has been very, very helpful, and we hope you will continue your work to spread the word not only in Africa and in the United States, but around the world, that this is the future of food. It is a great salvation for the 800 million to 1 billion people who go to bed hungry every night and who could be greatly helped by the advancement of biotechnology, something that not only is very, very safe, but also is very environmentally sound. And really, a way to help people who live in terrain and on land that isn't always suitable for production to have new advanced technology that will allow them to plant and grow useful and beneficial crops. So we thank you again for your contribution today.

Mr. KILAMA. Thank you.

The CHAIRMAN. We will now welcome to the table panel 4 and we have added the gentleman from panel 5 to this one unified panel, which includes Mr. Bob Stallman, president of the American Farm Bureau Federation, Washington, DC; Mr. Gary Joachim, member of the board of directors of the American Soybean Association, Claremont, MN; Mr. Leon Corzine, chairman of the Biotechnology Working Group, National Corn Growers Association, Assumption, IL; and Mr. Michael Deegan, president and CEO of the Agricultural Cooperative Development International and Volunteers in Overseas Cooperative Assistance, also of Washington, DC. Gentlemen, we welcome all of you. I again remind you that your full statements will be made a part of the record and ask you to limit your testimony to 5 minutes, starting with Mr. Stallman. Welcome.

STATEMENT OF BOB STALLMAN, PRESIDENT, AMERICAN FARM BUREAU FEDERATION, WASHINGTON, DC

Mr. STALLMAN. Good afternoon now, I guess, Mr. Chairman, and Ranking Member Stenholm, members of the committee. I am Bob Stallman, president of the American Farm Bureau Federation, and I am pleased to provide you with our views about the impacts of artificial barriers to trade and food aid in agricultural products produced through biotechnology.

Gaining access to international markets for products of agricultural biotechnology is one of AFBF's top priority issues. The promise of this new technology to farmers and ranchers and to people throughout the world has only begun to be realized. The opportunities of this new technology to improve agricultural productivity, to improve human health and nutrition, and to improve the world's environment are endless. We believe that any attempts by other

nations to block the import of products of biotechnology based on environmental, human, or animal health concerns, absent any scientific evidence, constitutes an artificial trade barrier and is unacceptable.

Mr. Stenholm already referenced this remark. I am going to repeat it, and frankly, I think it needs to be repeated around the world over and over again. There is no peer review scientific risk assessment that concludes that products of agricultural biotechnology intended for food use are inherently less safe to humans, animals, or the environment than their traditional counterparts. We are concerned about the ongoing discussions in the Conventional on Biological Diversity and its Biosafety Protocol, the Codex Alimentarius, the International Plant Protection Convention, the WTO negotiations on trade and environment, and in the legislative and regulatory bodies of dozens of countries throughout the world, that may result in the erection of artificial trade barriers for products of biotechnology.

It would take a lot of time to go through a lot of these examples in detail so I am only going to highlight a few, and the other esteemed panelists here will go into a much greater depth, I think, on specific commodity, economic, and market effects.

The most notable artificial barrier to trade of biotech products is the moratorium against new approvals of biotech products in the European Union. Widely agreed by most countries to be WTO inconsistent, the moratorium has cost U.S. growers hundreds of millions of dollars in lost sales since it went into effect in 1998. AFBF and more than 30 other agricultural organizations have campaigned hard to get the administration to initiate a WTO dispute settlement proceeding against the moratorium. We believe that a WTO decision, which we fully expect to be in favor of the U.S. position, is the only reasonable remedy available to U.S. growers either to lift the moratorium or impose retaliatory tariffs on EU products imported into the United States.

The EU's proposed solution to its biotech moratorium, which is the enactment of new rules requiring biotech products to be labeled and traced from farm to fork, are equally inconsistent with the WTO agreement on sanitary and phytosanitary measures and the agreement on technical barriers to trade. A WTO inconsistent solution to a WTO inconsistent problem is not acceptable. Mr. Chairman, this committee and the administration should not believe that the EU biotech problem will be solved if labeling and traceability rules are enacted and the moratorium is lifted. As proposed, the labeling and traceability rules only make the problem worse by erecting new, unscientific barriers to processed food products in addition to agricultural commodities.

The moratorium, and labeling and traceability rules will not be the last artificial barriers to agricultural biotechnology in the EU. There are indications that some EU member countries may require additional rules to be enacted to clarify environmental liability for agricultural biotechnology before they will vote to end the moratorium.

The ongoing EU moratorium has also fostered the imposition of artificial barriers to agricultural biotechnology in other countries. You heard about the African example from the previous panel. In

China, agricultural biotechnology is strongly embraced and research is significant. Biotech crops such as cotton, soybeans, and corn are produced in substantial quantities. Nevertheless, the Chinese government has recently used biotech regulation for the purpose of slowing or halting trade in U.S. soybeans.

New laws and regulations affecting products of agricultural biotechnology are being considered in 44 nations that have ratified the Convention on Biological Diversity and the Biosafety Protocol. These nations are attempting to comply with their obligations to this international environmental agreement that directs how member countries must treat living modified organisms. The United States is not a signatory to the convention, however, the terms of the Biosafety Protocol require U.S. shippers of biotech commodities to meet certain conditions before they can be accepted if the receiving country is a signatory to the convention. We believe this would be in conflict with WTO rules.

Mr. Chairman, winning widespread international acceptance of this new technology will be challenging and require considerable persistence. We appreciate the support of members of this committee on this issue. All of us need to continue to aggressively engage foreign governments to help realize the benefits and promises of agricultural biotechnology. Thank you.

[The prepared statement of Mr. Stallman appears at the conclusion of the hearing.]

The CHAIRMAN. Mr. Stallman, thank you. Mr. Joachim.

STATEMENT OF GARY JOACHIM, MEMBER, BOARD OF DIRECTORS, AMERICAN SOYBEAN ASSOCIATION, CLAREMONT, MN

Mr. JOACHIM. Good afternoon. Thank you, Mr. Chairman and members of the committee. I am Gary Joachim, a soybean and corn farmer from Claremont, Minnesota and member of the Board of Directors of the American Soybean Association. ASA represents 26,000 producer members on national issues important to all U.S. soybean farmers.

We appreciate this invitation to appear before you today to present our views on the impact of issues related to agricultural biotechnology on exports of U.S. soybeans and soy products. ASA is and has been a strong supporter of biotechnology. We have supported domestic and global policies that encourage its acceptance and growth. Since half of annual U.S. soybean production is exported, we recognize the importance of maintaining access in foreign markets for this technology.

As you are aware, RoundUp Ready soybeans were released for commercial production in 1996, after approval in the EU and Japan. This last year, 74 percent of the U.S. crop was RoundUp Ready. However, ASA is concerned about the possible disruption of foreign market access resulting from delayed approvals of other new biotech soybean varieties in major U.S. export markets.

In 1997, ASA sent letters asking the major biotech seed companies to not commercialize new soybean varieties until they have approved approval for import in our major customers. In the event a company chose to go forward with commercialization, ASA asked that they prevent the unapproved variety from entering the export market. ASA provided a list of conditions we believe must be met

to satisfy this assurance. Finally, ASA asked these companies to document that their production and marketing system met these closed-loop safeguards.

As a result of these measures, we are confident that the only biotech soybean entering the export market is the RoundUp Ready variety. However, delays in obtaining approvals in major foreign markets, particularly, the European Union, is denying U.S. farmers the ability to grow several new biotech soybean varieties already approved for U.S. planting. Clearly, the EU's actions are affecting the bottom line of U.S. soybean farmers.

U.S. exports of soybeans and soy products have been increasingly disrupted by the actions of the European Union. Despite having approved RoundUp Ready soybeans in 1996, the EU later enacted a mandatory labeling law which requires food manufacturers to stigmatizing GMO label on food products containing more than 1 percent of RoundUp Ready soybeans. This has caused food manufacturers who market in the EU to switch away from using U.S. origin soy protein or to reformulate their products so they are not using soybean ingredients at all.

In an effort to rationalize its inconsistent laws, the EU is preparing to adopt new regulations on mandatory tracing and mandatory labeling of biotech or biotech derived products that would further restrict access for U.S. soybeans and soy products. The traceability regulations require importers and food processors to trace biotech agricultural products and ingredients from farm to dinner plate under a paperwork intensive traceability and segregation regime. Compliance with this regulation would be costly, onerous, and unworkable given the realities of bulk commodity production, marketing, transport, and food processing.

The EU's proposed new labeling regulation requires that shipments of agricultural commodities or any food product ingredient containing more than 0.9 percent be labeled as containing biotech. It should be noted that the EU's proposed labeling laws do not extend to biotech processing aids, such as enzymes, amino acids, and vitamins produced by European companies and widely used in EU food production. The EU argues that such biotech products do not constitute a "material" part of the final product.

We have discussed this situation with administration officials, who have stated a willingness to consider filing a case with the WTO should the EU go forward with their proposals. However, we are concerned that once in place, these new regulations will be very difficult to repeal or modify. Even if the United States should win a WTO case, the EU could choose to pay compensation through other trade concessions that would not restore the harm done to our industry.

Meanwhile, Japan has taken a more rational approach that has not impeded our access. Japan has enacted a GMO labeling law that combines commercial best efforts to prevent mix-in of biotech derived commodities with a 5 percent threshold for labeling. This requirement has proven to be manageable for most exporters and food manufacturers, and our exports to Japan have not suffered.

China has emerged in recent years as our largest foreign market, however, its regulatory agencies have been highly unpredictable in establishing regulations governing imported biotech crops and

products. The result has been a stop and go roller coaster marketplace where contracting for new shipments of U.S. soybeans actually came to a halt for a time for fear that they would be rejected upon arrival at Chinese ports due to lack of acceptable documentation.

ASA strongly supported China's entry into the WTO and worked hard to obtain meaningful access for U.S. soybeans and soy products. The administration and Congress must continue to insist that China's leadership honor the commitment it made to President Bush that access to the Chinese market will not be restricted.

We had very telling testimony earlier this morning about the price developing countries are paying, and time precludes me from pointing out the many instances, and it would be repetitious where developing countries have restricted or even rejected U.S. food because of the fear and uncertainty raised by EU regulations. We all recall the tragedy of Zambia's government refusing U.S. origin food aid, which included soy products, due to its presumed biotech content. The governments of Zimbabwe, Mozambique, Malawi, Uganda, India, and Ecuador have all imposed restrictions that would have hindered the import and distribution of U.S. soy containing food aid.

Coincident with and impacting decisions being made by individual countries on biotech regulatory issues are ongoing negotiations to establish international standards governing trade and labeling. These include the Biosafety Protocol and the Codex Alimentarius Commission. Adoption of onerous biotech rules under the protocol or the codex would provide legitimacy to the EU's mandatory traceability and labeling regulations and encourage or require other countries to follow suit. Of particular concern to us, the Biosafety Protocol includes references to the precautionary principle, which is used by the EU to justify the use of unsubstantiated concerns about food safety rather than science based determinations. It is unclear whether the protocol would take precedence over the EU's sanitary and phytosanitary agreement and the agreement on technical barriers to trade, which require that trade restrictions be based on sound science. However, based on the EU's interpretation that the protocol should take precedence over the WTO, developing countries are already beginning to follow the EU example.

In our view, it is critical that Congress and the administration develop a comprehensive strategy to improve the environment for trade in biotech crops and their products. The strategy should include the following components: (1) The administration should immediately prepare WTO cases to be filed against the EU's planned traceability and labeling and novel food and feed regulations. Assurance that the United States will act forcefully will discourage other countries that are considering following the EU example. (2) The administration should continue enlisting the support of other countries for a WTO complaint over the EU's continuing illegal 5-year moratorium on biotech approvals. The United States must not accept imposition of the EU's traceability and labeling regulations as a condition for ending its moratorium on new biotech approvals. (3) Efforts by the administration to help developing countries establish an infrastructure for setting environmental and food safety standards should be significantly enhanced. (4) The administration

must immediately develop, identify a viable alternative to the Biosafety Protocol for regulating future trade in biotech crops and their products and work with other biotech exporting countries to achieve its rapid adaptation.

This concludes my statement, Mr. Chairman, and I will be glad to respond to questions.

[The prepared statement of Mr. Joachim appears at the conclusion of the hearing.]

The CHAIRMAN. Thank you, Mr. Joachim. Mr. Corzine.

STATEMENT OF LEON CORZINE, CHAIRMAN, BIOTECHNOLOGY WORKING GROUP, NATIONAL CORN GROWERS ASSOCIATION, ASSUMPTION, IL

Mr. CORZINE. Good afternoon. Chairman Goodlatte, Ranking Member Stenholm, and members of the committee, my name is Leon Corzine. I am a fifth generation farmer from Assumption, Illinois. My son, Craig, is a sixth generation, which allows me to be with you today. I am a board member of the National Corn Growers Association and chairman of NCGA's Biotechnology Working Group.

I would like to thank the committee for giving me the opportunity to speak today regarding artificial barriers to trade, food aid, and agricultural products produced through biotechnology. As shown, this topic is very timely, and I commend the committee and the chairman for convening today's hearing.

International acceptance to biotechnology is one of the largest challenges facing corn growers. This pressure will increase with the release of two new events this year. I can personally attest to the importance of this issue. The region I farm is impacted significantly by trade barriers and the use of new technology is restricted since Illinois exports a significant share of its corn and corn products. As a result, I am prevented from using these environmentally friendly systems.

Much has changed in the world market for corn in the 7 years since the introduction of biotech corn. To date, trade problems with biotechnology have had moderate influence on the overall U.S. export situation for corn. However, in some important markets, the influence has been dramatic, and we anticipate that the next few years may bring increasing pressures on U.S. corn exports as more countries introduce biotechnology labeling and approval systems and move to implement the Cartagena Protocol on Biosafety.

I would like to spend a few minutes summarizing some current and future biotech issues. This is by no means an exhaustive list. It also may be a little repetitive as things have been mentioned before. But first, in Asia, as led by Japan, remains our No. 1 region market for corn. Exports to the area have remained at about $2.2 billion over the past decade. However, there have been some important shifts in the distribution of the market, several attributable to difficulties with biotech regulation.

Japan has adopted a pragmatic approach to biotechnology. While they have instituted a program of labeling, they have limited it to a small segment of foods and have included reasonable commercial tolerances. The big question on biotechnology in Asia is China. As mentioned, China holds long-term promise as a market for U.S.

corn, however, trade disruptions experienced the soybean market could easily occur in corn as well.

The big success story for U.S. corn exports is Mexico, as their emergence as our second largest customer. While we have not experienced trade difficulties with Mexico due to biotechnology, we should recognize Mexico is sensitive to potential advantageous presence issues because of its position as the center of the origin of corn.

We are concerned about he recent controversy in Sub-Saharan Africa concerning the acceptability of U.S. corn. There has been a concerted campaign by some NGO's based in Europe to convince those hungry African countries that food that has been safely grown and consumed for years in the United States is unsafe, and if they accept this aid, they will somehow lose those export markets to Europe.

While we are concerned about the potential disruption of this outlet for U.S. corn, we are more concerned at the prospect for scare mongering about the safety of U.S. corn affecting the livelihood of citizens around the world. Let me emphasize Europe. They are the clear exception in the corn trade situation. The corn trade with Europe worth over $300 million per year in the mid 1990's has disappeared since 1998 due to the EU's inability to operate its own regulatory process. Even with the resumption of a predictable approval system in Europe, pending regulations on labeling of foods derived from biotechnology and on product tracing will likely make it extremely difficult for European food companies to use either U.S. corn or many of the food products made from corn. While we have lost the whole corn market in Europe, we continue to ship over a half billion dollars of corn oil and processed corn feed to Europe. Depending on how the new regulations are implemented, this market could be at risk as well.

Let me take this opportunity to thank Speaker Hastert, Chairman Goodlatte, and other members of this committee who recently signed a letter to President Bush urging a case in the WTO against the EU biotech moratorium. NCGA is thankful and we support your efforts wholeheartedly.

What is clear from a review of world regulation of biotech and corn trade is there is little consistency from region to region or from country to country. More than anything, we need to find some way to achieve international harmonization, or at a minimum, mutual recognition of regulatory systems for biotechnology in order to continue our trade in the future. Without sound science and confidence in regulatory regimes, fear will dominate. As mentioned previously, the Europeans convinced Africa, a continent riddled with starvation as we saw, that biotech corn is poisonous. If we allow this trend to continue, confusion and mistrust will rule, damaging all aspects of trade for exporters and importers alike.

Having described the challenges facing corn growers and agriculture, I do not recommend retreat. Our future as agricultural producers is linked to biotechnology and trade. The U.S. Government and organizations like NCGA need to promote the benefits of biotechnology while backing up those benefits with scientific analyses that gain and sustain the confidence of even the most skeptical

individual. This is a daunting challenge but one we stand ready to confront.

In conclusion, we look forward to working with the committee on solutions to these problems. I thank you again for the opportunity to address the committee. I would also like to, for the record, submit NCGA and U.S. Grains Council sent a letter to President Bush concerning WTO action, and I would like to submit that, if I could.

The CHAIRMAN. Without objection, it will be made a part of the record.

Mr. CORZINE. Thank you very much.

[The prepared statement of Mr. Corzine appears at the conclusion of the hearing.]

The CHAIRMAN. Thank you, Mr. Corzine. Mr. Deegan, welcome.

STATEMENT OF MICHAEL W. DEEGAN, PRESIDENT AND CEO, AGRICULTURAL COOPERATIVE DEVELOPMENT INTERNATIONAL AND VOLUNTEERS IN OVERSEAS COOPERATIVE ASSISTANCE, WASHINGTON, DC

Mr. DEEGAN. Thank you very much, Chairman Goodlatte, Mr. Stenholm, other members of the committee. Since 2001, ACDI/VOCA, which is a PVO affiliated with the National Council of Farmer Cooperatives, has conducted regular surveys of U.S. officials, private sector representatives, and international organizations on the subject of GMO issues in food aid programs.

Mr. Chairman, we have found that concerns have gradually increased and that GMO issues are now a significant impediment to food security in some low income food deficit countries. This growing problem can be attributed to efforts of advocacy groups to curtail GMO's, and we have firsthand experience taking on Greenpeace in Georgia in a Bt potato program; the increased media attention to the political aspects of the GMO issue; continuing resistance from the European Union to GMO's; and increased desire on the part of developing governments to play a regulatory role in areas that they are not fully qualified to participate.

In 2002, U.S. food aid reached nearly 4.7 million tons. Of that total, approximately 1.5 million tons were corn, soybeans, and related products. Thus, roughly 35 percent of U.S. food aid could be considered as having varying degrees of GM content. Food-insecure people pay the dearest price because of the GMO controversy, but there are other drawbacks. PVO's have increased operating costs due to troubleshooting that they have to do relative to the shipments. More expensive commodities often have to be substituted to make up for caloric deficiencies. Commercial markets for U.S. commodities may suffer when a food product's image is tainted. The potential for GMO based domestic food production increases is reduced. PVO's incur financial risk if commodities are held up by the recipient country, and that can be in ship per diem at $6,000 a day or storage that is not necessary, which is at market price and pilferage.

There is no international consensus on the acceptability of GMO foods. You have heard about the Codex Alimentarius Commission early today. Mr. Stenholm addressed it directly, but there is no conclusion. The bottom line is the ultimate responsibility for accepting the food aid containing GMO's would rest with the recipi-

ent government. They are the ones that make the decision. USDA contends that biotech developments undergo a rigorous evaluation and approval based on U.S. laws and regulations which have health and safety as their primary goals, and that once a plant variety passes regulatory review, it can be used like any other food. Food aid commodities are the same as those consumed by Americans every day. Our Government does not believe that the food production and distribution system can reliably separate GM foods and their non-biotech counterparts.

Our Government has launched education programs in food aid recipient countries to clarify the U.S. regulatory process to address host country concerns, to correct misconceptions concerning the health and environmental implications of biotech products and to develop foreign markets. Congress wisely included a provision in the current farm bill, authorizing USDA to establish a biotech and agricultural trade program to remove resolve or mitigate significant regulatory non-tariff barriers to the export of U.S. agricultural commodities in section 1543(a).

You heard about several of the problems that GMO foods have encountered by other speakers. In Uganda, which is one of our major countries for providing assistance to HIV/AIDS families, we have had shipments confiscated by Ugandan custom officials concerned about GMO soy products. After intensive discussions and lab tests, the commodities were released but the Ugandan government legislation has not been approved, and we are anticipating continuing problems. We are feeding some 70,000 families who are HIV positive every month with food aid CSB (corn soy blend).

You heard about the southern Africa problems, in Zambia and in Zimbabwe. Mr. Joachim covered the ASA side of the issue. It is terrible what has happened. The Zambian ban on GMO food aid will be a major hurdle in preventing starvation of over 2.9 million people who need 21,000 metric tons of food aid a month. New GMO guidelines have been submitted to the Zambian cabinet for review, but none of the details have been made public. With half of 12½ million people at risk of starvation, Zimbabwe relaxed its previous hard line stance on GMO's and allowed the introduction of U.S. corn that had already been milled and thus would not endanger the export potential of their local corn. The government of Zimbabwe is currently working to develop a biosafety screening system. It is not clear what form that will take.

In Bolivia, Bolivia banned all food aid and food imports from the United States during March and April of 2001 due to GMO concerns. Food aid being managed by ADRA, CARE, and Food for the Hungry International was affected. ADRA was forced to store flour in warehouses for 7 weeks at considerable expense until the ban was lifted.

Congressman Wolf covered the problem in India, and it kind of gets me because India is now big in Bt cotton. So it really raises some questions of whether it is the science or whether it is the politics.

The PVO views are that food aid programs that utilize GM commodities are accepted provided that the commodities have demonstrated to be safe through an independent transparent and scientifically based approval system as we have. Restricting geneti-

cally modified commodities and products from food aid programs would be extremely detrimental to addressing immediate food needs around the world. It is the responsibility of the U.S. Government to address the issues raised by the recipient governments as to the acceptability of GM modified food aid commodities.

ACDI plays a major facilitating role in communicating the recipient government's concerns and providing support documentation.

The CHAIRMAN. Mr. Deegan, if you might bring your remarks to a close?

Mr. DEEGAN. I definitely will, sir. Real quick, the administration should accelerate its implementation of the points agreed to in a conference with PVO's that they had last fall. We would like to see this happen. USDA should develop and publicize the implementing section of 1543(a), the farm bill. The USDA has established the biotech team under the general sales manager and we applaud them for that.

Dr. Kilama and Dr. Juma talked about the training. We need to get back to the professional degree programs that we had in the early 1980s. We had 8,000 students in agriculture degree programs in the land grant colleges at that time. We are now down to fewer than 200, and these are the guys, the gentlemen, the graduates go on to be the leaders, the ministers, and the professors that make the difference.

We also need to enhance the support for the agriculture programs at USAID in the Economic Growth and Agriculture Bureau. Secretary Veneman is taking on an agriculture ministry and hosting this out in Sacramento in June. GMO's will be a major part of this ministerial that she is hosting. And USDA and USAID will also be addressing the GMO food aid issue at the annual Food Conference, April 15 through 17 in Kansas City. Thank you, sir.

[The prepared statement of Mr. Deegan appears at the conclusion of the hearing.]

The CHAIRMAN. Thank you, Mr. Deegan, for your very helpful testimony. Gentlemen, let me ask all of you, if the European Union lifts its moratorium on biotechnology approvals and then implements the traceability and labeling requirements, do you see any potential for change in agricultural trade levels? Will the problems generated by the new rules be as bad as the moratorium itself or perhaps even worse? Mr. Stallman.

Mr. STALLMAN. Mr. Chairman, I believe that we will be in a worse situation if that turns out to be the case. Those labeling and traceability rules I think expand the problems that we currently have under the moratorium. It has been clear from some in the retail food sector that they, in essence, will be impossible to comply with, and will certainly affect the sourcing of products now that are sourced from U.S. sources. So just in summary, I think we would be worse off. I think the rules for WTO are inconsistent as they are proposed now for labeling and traceability, and whether or not we have a challenge on the moratorium or labeling and traceability both, I think we will have to challenge that in the WTO dispute settlement process.

The CHAIRMAN. Thank you. Mr. Corzine.

Mr. CORZINE. Mr. Chairman, I would concur. It really gets down to some negotiation with our government, and you get to tolerance

type issues and what we can truly do and what we cannot do. In one sense, it could be worse, because some of the new regulations will address and make things tighter for feed products, as well, and labeling of those, which is not there currently, so that is another shift that is definitely in the wrong direction.

The CHAIRMAN. Are there biotech products that are currently approved here in the United States but are not being used by farmers because of their concerns about the attitudes against biotechnology in Europe and some other places around the world?

Mr. CORZINE. If I may, Mr. Chairman, yes, there are.

The CHAIRMAN. Yes, sir.

Mr. CORZINE. We have several products that are very good, very environmentally friendly products, and as I mentioned, we have two new products this year that would be very helpful in my region, in particular, but across the Corn Belt, that we are not able to use because of corn products going into Europe. We could cut our chemical use on the insecticide side, not completely, but we could cut them by half to two-thirds or maybe even three-fourths with the root worm technology that has just been approved by Monsanto. And Dow and Pioneer are also working on a root worm product that will be here soon.

We are glad that the industry is going ahead with the investment in technology, even with this problem, but it is very serious. Like I mentioned, my son is a sixth generation on our farm. He runs the planter, and there are many cases and issues of handling these toxic chemicals, that if we could reduce those with this new technology, it would be very good, as well as it would help on the yield side. But primarily, from the environmental side, there is also RoundUp Ready corn and a couple of other products that are not approved in Europe that we have to hold back from in my area.

Mr. JOACHIM. Mr. Chairman, I might say that the situation with soybeans is pretty similar. We have at least one event, which is Liberty light soybeans, that has been approved in the United States, and it has been sitting on the shelf in the EU since 1998, I believe. And it is not—if this was approved in the EU, so that our farmers would feel safe to go ahead and plant it, it would give us another choice, and it would also end the de facto monopoly that the current herbicide tolerance trade provider currently enjoys. That should help lower our cost, and make us more competitive on the world market if these approvals could move forward.

The CHAIRMAN. What kind of outreach and education has the American Soybean Association and other groups done to show the world market the benefits of technology?

Mr. JOACHIM. Well, the American Soybean Association has been active since before I got on the Board, I believe since about 1995 or 1996, even before the product RoundUp Ready was commercialized. In fact, we had people in Europe, two farmers in Europe right now, today, on a mission trying to inject some sanity, we hope, into the European approval process and into the new regulations. And it has been one of the things that we spend an immense amount of time on, really, I think, time in some instances, we could spend better off dealing with not problems, but areas that need addressing in the United States, such as environmental protection. And actually, some of these lack of approvals, really, are detrimen-

tal to the environment because it makes it harder to use no-till and all, so to a certain extent, we are using more chemicals that aren't as friendly as the biotech soybeans would allow us to use.

The CHAIRMAN. Thank you very much. The gentleman from Texas.

Mr. STENHOLM. Thank you, Mr. Chairman. Mr. Stallman, your statement that I mentioned in my opening remarks bears repeating again. The American Farm Bureau Federation has yet to discover any peer reviewed scientific risk assessment that concludes that products of agricultural biotechnology intended for food use are inherently less safe to humans, animals, or the environment than the traditional counterparts. And not only have you not been able to find it, no one has been able to find such a peer review. Now, there are those that will find their opinions, and they are expressed. Greenpeace was mentioned, for example. Everyone is welcome to their opinion, but when you have that opinion, and then translate it into political decisions that have the effect on trade that basically will stop technological development, more reasonable heads need to get involved in this. And that is where the previous panel, talking about education, is so important, and what you are doing through your various associations is so important.

The WTO requires a member country to treat imported products the same way it treats domestically produced products. How will, or does, the EU justify its exemption from its labeling and traceability regulations for the biotech processing aids that were mentioned in your testimony, enzymes, amino acids, and vitamins, in light of its failure to exempt soybean oil derived from biotech soybeans? How do they do that?

Mr. JOACHIM. Well, I think, Mr. Stenholm, this is a clear example where a person, or an institution, or a country can hold two somewhat diametrically opposed concepts in their mind at the same time. We don't think they really can do that. They just do it.

Mr. CORZINE. I would concur with that. That is what I found. I have been over there a couple of times. In our organization, we team up both with the Farm Bureau, and the soybean folks, and the U.S. Grains Council on missions to Europe, and find the exact same thing. They just ignore it. You bring it out and it is like they just turn the page. So we need to push harder on that, I believe, and I do think the timing, I would add, is right, not only for this meeting, but I find the Europeans are somewhat backpedaling because of what has happened in Africa. And we need—our government can push on their government. They have let their NGO's, which they helped fund, run rampant on this issue, and I submit that they could quiet those down quite a bit and help reason to prevail.

Mr. STENHOLM. I would give a little advice to our European friends on this. Mr. Stallman, I agree with your answer a moment ago regarding the trace back and the traceability, the labeling question. Be careful what you ask for, you might get it. The inconsistencies of this debate, when you start exempting some and not others, you are going to find yourself in a hole you can't dig yourself out of, except politically, and that is going to destroy trade. Ultimately, it will destroy trade, but even more importantly than that, it will destroy the development of technology.

Final question, this year the Cartagena Biosafety Protocol is expected to be ratified. The protocol will influence the movement of lab modified organisms, and therefore, trade in agricultural products. What are the likely impacts on U.S. agriculture producers and exporters from this? Mr. Stallman.

Mr. STALLMAN. Well, as I think I referenced in my statement, once it is ratified and once countries that are signatories start trying to comply, we think that will put up a barrier to the importation of products derived through biotechnology that is WTO inconsistent. The problem is there will have to be a determination, whether the Biosafety Protocol trumps WTO trade rules, or are we going to abide by WTO trade rules which says there has to be science and reasons for putting up barriers like this. So once again, that will be another case, I think, in the making, and there will have to be a determination as to which agreement, which treaty, has priority. The Europeans and other countries would say that the Biosafety Protocol would take precedence over the WTO. That is what they are trying to say. We think they are wrong. And ultimately, that issue will have to be resolved.

Mr. STENHOLM. I appreciate very much Chairman Goodlatte's interest in this, and I assure you that we will be working together. I know he will be leading us in proper oversight of these treaties, so that we take a good hard look at these agreements before, ultimately, anything is voted on in the United States Congress. Thank you all very much for your testimony today.

The CHAIRMAN. I thank the gentleman. The gentleman from Michigan, Mr. Smith.

Mr. SMITH. Mr. Chairman, thank you. Probably the greatest potential advantage to genetic technology is in the developing countries, where we have the potential now of picking out one or two genes and implanting them or taking them out of a different food product, and having a food product that can grow in outlying soils or under climatic conditions that some of those countries can't grow food products in. And when you talk rationally, in our Science Committee, as I mentioned earlier, we had three hearings, and Mr. Chairman, we also brought in Greenpeace and some of the anti-organizations, and even testimony with the European Union.

And of course, our argument is that, traditionally, where you have maybe 25 to 35,000 genes in a particular plant product, and you either through crossbreeding or even hybrid breeding, you are taking a chance of what genes might turn out, and historically, we have come up with some poisoned products with that kind of cross breeding. Now we have the ability to know what the characteristics are of that particular gene and not have that extra risk. And when you add to that the oversight that we have in this country, unlike most other countries, that I think make some of those other countries nervous, our oversight in regulatory oversight in food and drug, and USDA, and EPA, still, the reaction in the debates with the European leaders are, well it is we are simply going on what consumers want to buy. But as we proceed on WTO negotiations, I think part of what we need to insist on is that a country that lets emotional rather than scientific information prevail in this discussion, needs to have some kind of responsibility to give the scientific information.

And of course, what Greenpeace goes on is what they call or what we call the precautionary principle is you don't know what its effect on 10 generations from now might be on whether it is the monarch butterfly or whatever. And so they have emotionally convinced enough people that there is some danger, and that is one reason, of course, that we have problems throughout Europe and Japan.

But the other problem is that I think, and this is what I want your evaluation on, that there is a real effort to use this as an excuse to keep out some of the competition; namely, American competition. And if we are going to get our foot in the door meeting with the scientific community in the Netherlands, they said, well, look, why don't you produce something that helps people. And of course, what we are doing, it helps farmers a little bit, it helps maybe the environment, a tough discussion a little bit, but we sort of lost as allies the pharmaceutical industry that nobody complains about. But our effort and where does the money come from to produce those kind of golden rice or other efforts may be other than government, but it seems to me that it would behoove the agricultural community also to contribute towards the development of research that can add the vitamins, the minerals, the kind of food product than can help the cure of the blank banana disease.

It seems like we have to get our foot in the door to develop the kind of product that consumers say, boy, this is really going to make me thin so I don't have to exercise, or I use that as maybe give me your reaction. Because what we are pushing is something that helps us farmers a little bit be more productive. But in terms of people saying, boy, I want to buy that product more than maybe the 2 or 3 cents that they experience in a reduced cost because of increased productivity. Just any comments you might have.

Mr. CORZINE. If I may, maybe I will start off. We are able to make the argument very clearly that with the Bt corn product, corn bore product, for example, that it does help us produce a higher quality product, and that resonates well in some places, because with less insect damage to the grain, you get better shelf life, and you can move forward with better products provided to the customer. But as you say, we have pushed very hard on the biotech providers from the corn side to get these other products with direct consumer benefits developed, and there are some very close. There are some that even address some of the fatty acid issues, that if you use that particular grain, why, it is almost as healthy as eating fish, for example, rather than incorporating some fish into your diet rather than all beef.

Those kind of things are on the horizon. They are very close, as well as other areas of the vitamin benefits and things that will be there. Maybe in some of the plant derived biologics we have those issues as well, which is a whole other area. But to help provide cheaper drugs to humanity to take care of hepatitis and other kind of things are on the horizon.

Mr. SMITH. Several years ago, and I was a little disappointed, but several years ago out in a WTO conference in Seattle, the agricultural community, I think, got sold a little bit of a bill of goods on separating the pharmaceutical decisions in biotech away from

the agricultural decisions because nobody is complaining about the great drugs that we are producing through biotechnology.

Mr. CORZINE. That is accurate. I concur.

Mr. SMITH. Thank you, Mr. Chairman.

The CHAIRMAN. I thank the gentleman. The gentleman from Minnesota, Mr. Peterson.

Mr. PETERSON. Thank you, Mr. Chairman, and thank you for your leadership in calling this hearing. A lot of my producers are very interested in these issues. I would like for you to give me your assessment of the apparent strategy of the administration postponing initiating a dispute in the WTO over the EU moratorium on the approval of these GM crops.

Mr. STALLMAN. Well, we have been actively, as an organization along with many other organizations, encouraging the filing of a case, feeling that we are sort of at the end of our rope and it doesn't look like there is much progress being made over in Europe with respect to the moratorium. Interestingly enough, I even had one EU official who remained nameless that indicated that we probably would have a better WTO case on the labeling and traceability rules, not that we want to have them implemented first to have to take the case. We have been strongly encouraging the administration. USTR was supportive of that. USDA Secretary Veneman was supportive of that. And although I think we understand that now, given the events that are going on in the world, in Iraq, that we would be distracted in our focus in trying to go forward right now. So it is not that we don't want it. We want it, we want it as soon as it is feasible and as soon as can focus our efforts on achieving a successful outcome. So we view this as sort of a temporary respite, I guess, as we resolve some other issues in the world. But we are going to continue to strongly encourage the administration to go ahead in the filing of the case.

Mr. PETERSON. And I assume you all agree with that?

Mr. CORZINE. Yes.

Mr. JOACHIM. Yes.

Mr. PETERSON. Do you think that farmers would be better off if we brought this to a head rather than to wait around? Do I understand where you are at?

Mr. STALLMAN. There is one addition to that, and I think there was kind of a question imbedded for another panel. There are two other reasons why that aren't directly related to the EU rules, that we need to be firm and move forward with the case. The one is prevent the spread of the EU disease precautionary principle, the idea that we can use these trade barriers, unscientific trade barriers, to prevent products from being in other countries, or looking at the EU playbook and trying to figure out ways to do the same thing, and that is one reason. And the other reason is domestic. Our producers, agricultural producers, have been supportive of trade in the past. We hope they will continue to be supportive, but that support is going to be conditioned on our government showing that we are willing to enforce the trade agreements that we have and this is the category that this falls in. If we can't enforce trade agreements that are in place, then we lose confidence in that whole system.

Mr. PETERSON. Mr. Joachim, what is the outlook for U.S. exports of soybeans to China in 2003?

Mr. JOACHIM. Mr. Chairman, in 2003—well, so far this year, we have exported a little over 200 million bushels. That was, obviously, from the 2002 crop. Assuming we have a normal crop, I would think we would be someplace in the same ballpark in the next marketing year. That is a little bit like asking—pretty soon, you are going to ask me what the price is going to be, and then I will really have to claim ignorance.

Mr. PETERSON. What is your view on the possible extension of China's interim approval system?

Mr. JOACHIM. Well, so far, we are quite confident that the Chinese are doing what is best for China, and it has been our feeling, but we have no way of knowing this for sure, that one of the reasons they have had this stop and go approval is to withhold for a tiny time window. Our crop and the Chinese crop, obviously, both have the same window. They are both grown in the Northern Hemisphere. And we think that one of the reasons that they have in the last couple of years have had this process is just to perhaps slow down U.S. shipments initially to protect their own farmers. So we are quite confident that these are really—we don't think that these are really deep felt convictions on the part of the Chinese and that they are going to stop trade by any means.

Mr. PETERSON. The administration has kind of adopted a wait and see attitude here, too. Do you have the same position here, that we maybe ought to be more aggressive and try to——

Mr. JOACHIM. Well, I think the administration, which I didn't have time to go into that, but the Chinese have asked for some trials that are actually duplications of what has happened in the rest of the world. I really think they are unnecessary, but they are going on, and it looks like they should be completed. And I guess we think in the instance of China, we think that they have probably done a pretty good job of bringing the subject up at the highest levels so far, at least in the past.

Mr. PETERSON. So you don't think we need to be more aggressive than we have been?

Mr. JOACHIM. Well, we think we always need to be—and I was going to make the point in response to the last question, that often times we are more interested in negotiating the next trade agreement than we are in enforcing the current one, and that is something that we think we really have to hold everyone's feet to the fire, farm organizations, the administration, that if nothing else, to maintain support for trade in the farm community to show that we are serious about enforcing the agreements that are currently on the books.

Mr. PETERSON. Amen. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much. The gentleman from South Dakota, Mr. Janklow.

Mr. JANKLOW. Thank you, Mr. Chairman. This reminds me of going to law school. They tell you that if the facts are against you, you argue the law to the jury. If the law is against you, you argue the facts to the jury. And if the facts and the law are both against you, you have to bring in a smokescreen for the jury. We waste our time talking about science. Unless someone in the world can come up with a scientific study, a peer reviewed scientific analysis, a conclusion by any scientist of any persuasion that lends creditabil-

ity to the argument there is something wrong with these, we waste our time talking about it. These are political problems. Part of our problem is we sit around in America jacking our jaws about it, talking all the time, all the things we should be doing. They don't even know we are meeting, and if they did, they would turn it off. They could care less. They are not impressed with us on these kinds of issues, the Europeans aren't. It reminds you of the old adage, full of sound and fury signify nothing.

Either we are going to make a decision to enforce the laws and treaties of the United States or we are not. One of the things we are all told all the time is, in the Constitution, it says something like this constitution and laws and treaties passed hereunder shall be the supreme law of the land. That means someone has to enforce them. It does us no good to talk about it. If we are not following the existing treaties and laws, why pass more?

So I guess what I am saying is, recognizing that the Europeans have been rather successful in scaring themselves, given the fact that the information you and the other witnesses give us indicate Spain, Portugal, Ireland, and Finland, so far have moved in the direction opposite of the rest of the European community, that countries that have the unbelievable starvation, hunger, deprivation, and abusive people, like we have all seen not only on just that little film this morning, but over and over and over in our lives. And yet, those governments will not accept free food for their people because they are afraid some export may not be accepted in another country. What do you suggest we really do? Is there something we can do or, I mean, we all have fun talking. Should we just continue to talk about it? Do any of you have a suggestion of what we can really do?

Mr. CORZINE. The first thing I think we should do is really push forward, as was mentioned, with the other situations in the world. But this WTO action I think is very important. I think we have caught the Europeans on this issue, are backpedaling somewhat with what has happened in Africa and trying to deny their responsibility. And I think in not only the WTO action, but in our other negotiations with them, they try to shed responsibility for their non-government organizations going ahead and doing things, and being wild out there with all these things that just aren't true, and fanning the flames of emotion. And I don't believe we should let them shed that responsibility because they help fund them.

Mr. JANKLOW. Maybe every tourist that goes to Europe ought to carry a pocketful of this stuff and just throw it around like Johnny Appleseed used to do it.

Mr. CORZINE. I do think the mood has changed somewhat in my last time there because we are having some good dialog with the French corn growers, and they want these products as well. And so I think we have to operate from within.

Mr. JANKLOW. But sir, we have been operating from within for decades, literally, a couple of decades. There is no light on the horizon, and waiting for French farmers to lead a revolution in Europe towards the advancement of the opening up of trade, I think is beyond the realm of imagination of most of us. It used to be the intervention price in wheat. It has always been something and it isn't going to change now as they continue to protect their domestic sup-

plies of food. And so other than that, if there is anything you think we can do, tell us. Maybe we can't get it done politically between us, but on the other hand, just maybe we can. I think everybody is at wit's end, but holding hearings which the chairman has done that lay this out before the public ought to be, what is the next step.

Mr. JOACHIM. Well, this morning, Mr. Kilama and Mr. Juma, and I hope I didn't butcher their names, mentioned the need for education. I think that is part of it, but I don't know what we can do besides on the one hand educate and on the other hand proceed with all legal avenues that we have, such as the WTO. I don't think we should be scared. First there is a lot of steps that happen before you formally file the case, and so I don't think we should be scared off by the fact that—I mean, they are so mad at us now anyhow, I don't think it could be much worse over this issue.

Mr. JANKLOW. My time has expired. Thank you.

The CHAIRMAN. I thank the gentleman. It is a very good question and I think there are some answers. We will get to that in a moment. I have one more question and I would like to direct it to Mr. Deegan, and it is along the lines of what the gentleman from South Dakota is asking, and that is what else can we do.

It is my understanding that most private volunteer organizations have taken somewhat less of an advocacy role with regard to this issue, opting for a neutral position, and I don't understand that. Don't you think it would be in the best interest of the needy and developing countries that such organizations embrace this technology as a solution to many of the sustainable development problems that they have, the problem not just of starvation but of being able to grow their own crops in a sustainable fashion, and shouldn't you be out there advocating that in a positive light?

Mr. DEEGAN. Mr. Chairman, you have asked one of the advocates, ACDI/VOCA, there is a lot of technology transfer and several of our programs embrace biotechnology as the key element. Just to give you a good example, in Kenya, we are running a maize program which is introducing new varieties of Bt corn into the Kenyan market. There are several of our other PVO's and NGO's that do not embrace biotechnology and a lot of it is personality driven. It is the nature of the organization that drives that neutrality so that they say we don't get into the political issues. We want to just be neutral about this.

The CHAIRMAN. But it is not a political issue if you are simply promoting good science and good technology.

Mr. DEEGAN. And I agree with you, and I think Mr. Joachim covered that in his comments. I think we have to keep the heat on. We have got to be out keeping the pressure on. We have got to increase this education, especially, in the African arena. We have got to be pushing forward. We have got to have partnerships with the companies that are developing the GMOs. That is extremely important, and we do. We have worked hand in glove with Monsanto on one of their products. They were contributors in a partnership that we took forward and we are anxious to get out there and do more of it. And I think staying the course is going to be the big issue.

We have come a long way in 6 years. You look at the number of acres or hectares that are in soybeans around the world. You

look at the countries that are in the business now, where they are up from six to 16 that are participating in major GMO crop activities. It just comes back to that European influence that we run into in several of the former colonies of European countries. So I just say, let us just hang in there, because science will win this in the long run.

The CHAIRMAN. Thank you very much. If that doesn't prompt any other questions, I have a few housekeeping matters and we will conclude.

I indicated that the committee staff couldn't recall the last time a Speaker of the House of Representatives had testified before the Agriculture Committee, but in deference to our clerk, Mrs. Gingrich, I need to note that former Speaker Newt Gingrich testified before the committee in 1997. So we want to set that record straight. It has been 6 years, but we are glad to have a Speaker back.

I want to thank this panel of witnesses for their excellent contribution. I would say to the gentleman from South Dakota and others who have the same question I do, which is what do we do next. I think there are a number of things that need to be done. We do need to press forward with the WTO case. Once Europe does end this moratorium, which I am confident they will, we are going to encounter, as the witnesses testified, a greater problem with the traceability and labeling requirements. But I think we need to push forward on both fronts, both in terms of once we are able to introduce biotech products into Europe to do that, and to market them and to sell them. I think they will get growing acceptance because when you meet that labeling requirement, you are going to be able to say this is GM, and as a result, it is better because it will do this for you. The product does not have as much pesticide usage. The product has helped environmentally. The product has better taste. The product has additional vitamins. The product has all kinds of benefits that can be advertised and promoted.

Second, we need to make the point again and again that we are not trying to get anybody to eat anything that they don't want to eat. And so for whatever suspicions remain for whatever reasons, we need to make sure that we are able to introduce into Europe products that are not GM and sell that product to customers who want to have that product. And therefore, we need to push for fair requirements for the separation of that product from the GM products.

And finally, again, I want to thank Dr. Kilama and Dr. Juma, and let them know that we appreciate their efforts to continue this education process, which is vitally important. We truly are at the cutting edge of a great future for ending hunger and starvation around the world. Biotechnology clearly has to take a leading role in that, and so educating folks everywhere, not just in Africa, but in Europe, in the United States, and elsewhere around the world, about the importance of promoting science and technology and defeating ignorance is part of the future, and we thank them for their contribution.

I thank all of you for your contribution today, and without objection, the record of today's hearing will remain open for 10 days to receive additional material and supplementary written responses from witnesses to any question posed by a member of the panel.

I would also like to submit two statements for the record. Statement No. 1 is a letter signed by 3,300 scientists from around the world in support of biotechnology, including, I might add, a number of European scientists. There are at least 45 different biotechnology research laboratories in Europe doing great work and are greatly frustrated. I know because I have met with some of them. They are greatly frustrated by the policy in Europe today which is hurting their good work as well. Statement No. 2 is testimony that was received by Dr. Florence Wambugu. Dr. Wambugu is the president of an organization whose goal is to promote the adoption and development of biotech crops in Africa. I appreciate her submission.

The gentleman from Michigan.

Mr. SMITH. If there is no objection, could I include in the record the summary of the three hearings that we had in Science Committee called Seeds of Opportunity?

The CHAIRMAN. Absolutely. Without objection, we will include that valuable information as well.

This hearing of the Committee on Agriculture is adjourned.

[Whereupon, at 1:10 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF JOHN KILAMA

Thank you, Chairman Bob Goodlatte, and Mr. Charles Stenholm, ranking minority member, for providing me with the opportunity to speak to you and the committee today about the challenges that face the United States, as we attempt to overcome widespread apprehension about biotechnology, and the American role in biotechnology.

As president of the Global Bioscience Development Institute, my goal is to help leaders of developing nations overcome the apprehensions—so that they acquire a sense of ownership regarding biotechnology. Only when their reluctance is overcome will it be possible for those countries to acquire biotechnology and thus allow the United States to fully develop trading relationships with them—and working with the countries to exploit the vast potential of biotechnology as an engine of their economic growth.

Most of my remarks will concern how those apprehensions affect adoption of biotechnology in Africa and hinder development of trade with the United States. I will also say a few words about China and India, and my views about prospects in those countries.

WHY APPREHENSIONS

No news story dramatizes the challenges confronting the biotechnology sector more dramatically than the refusal by Zambia and other southern African countries to accept American food aid processed from genetically modified crops last October. Although nearly three million Zambians are facing famine, many Zambians feared that genetically modified food aid could be used to grow new crops—and enter the local food chain—with dangerous effects. Elsewhere around southern Africa, some 14 million people are at risk of famine—yet reluctance to accept any food products derived from genetically engineered crops is widespread.

I want to offer my perspective on the critical reasons for that reluctance—and how it affects the prospects for closer trade ties between the United States and Africa. My views are derived from my experience training selected leaders from 39 Sub-Saharan African countries—in the practical skills they need to acquire to develop and implement effective policy on biotechnology, biosafety and related issues.

I believe there are four major reasons why so many Africans are having difficulties in adopting biotechnology. Each reason provides a compelling perspective on the challenges that face America' trade and technology ties with Sub-Saharan Africa.

Those reasons are: Africa's close economic ties with Europe. Africa's inability to create biosafety laws and effective biotechnology policy. The capacity crisis within African government institutions. The unprecedented barrage of negative publicity from opponents of biotechnology.

TRADE ISSUES

The first reason concerns Africa's close trade relationship with Europe. As you know, the nations of Africa are among the more than 130 countries that have agreed to the Cartagena Protocol on Biosafety of 2000, known as the Biosafety Protocol. This global treaty, though not ratified yet, was conceived as a vehicle to address the potential environmental impact of the movement of living, genetically modified organisms (GMOs) across national boundaries. The goal of the Biosafety Protocol is to allow countries to assess the environmental or adverse impact of GMOs on human health.

Unfortunately, many countries have embraced the strategy of Precautionary Principle of the Biosafety Protocol in order to exclude genetically modified crops. The Precautionary Principle states that even when there is a lack of scientific certainty, countries are allowed to block the import of GMOs—if they are concerned about potential environmental damage.

Articles 10.6 and 11.8 of the Protocol state that, Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism . . . in order to avoid or minimize such potential adverse effects.

Clearly, the Precautionary Principle was intended as a tool to safeguard any potential environmental or health problems that could arise from GMOs; the Principle was not intended to be a non-tariff barrier to trade. It is clear that some countries are using the Precautionary Principle has a pretext to legitimize their refusal to accept genetically modified organisms.

To date, there is no credible scientific evidence that any foods derived from genetically modified crops have an adverse impact on human health or any environmental degradation. Despite the fact that there is abundant information about the safety of genetically modified foods, many countries in Africa continue to be reluctant to move quickly to acquire the biotechnology to support their agricultural programs.

I believe that the real reason for their reluctance to accept GMOs has more to do with Africa' fear to offend its close trading partners in Europe. Africans are concerned that Europe will retaliate against African exports if Africans accept genetically modified organisms from the United States. Southern African leaders have concerns beyond the safety of GM foods. Roughly half the region's agricultural exports are sold to the European Union, where there is loud opposition to GM foods, and where they must be labeled as such. African farmers are concerned that if they are no longer able to certify that their foods are GM-free, they will lose their share in the European market.

These European markets are an important source of income for southern Africa's cash-starved economies. From 1999 through 2000, for example, Zambia exported more than 8,400 tons of produce to Europe, earning U.S. $62.6 million. Between 1993 and 1997, Zimbabwe's export of peas to the European Union grew by 53 percent, so that Zimbabwean products now account for 12 percent of all peas and beans consumed on European tables.

"Our decision to reject some of these foods is out of fear...we have been told that we will lose our European market if we start growing GM foods," Zambian Vice President Enoch Kavindele has explained to U.N. aid workers. "Hungry we may be, but GM foods pose a serious threat to our agriculture sector...and [could] grind it to a halt."

Another example is Botswana. Although Botswana exports beef to Europe, Botswana is somewhat reluctant to move forward in accepting biotechnology out of concern that the European Union will retaliate.

Clearly, as a result of Europe's historic role as a colonizer of Africa, Europe's influence in Africa is far greater than that of the United States. Decades after the demise of colonialism, African exporters of agricultural commodities are far more dependent on European markets than American markets.

Why is Europe so opposed to genetically modified organisms? Others may have a better perspective on the full range of factors. However, in my view, Europeans may be trying to buy time until they are in a position to compete effectively with the US. The Precautionary Principle of the Biosafety Protocol serves as a convenient tactical device for Europeans—because the Principle permits countries to reject foreign GMOs even when there is no scientific proof that they are harmful.

A Shortage of Strategic Policymaking

A second set of reasons for Africa's reluctance to accept biotechnology involves the inability of African governments to develop a coherent strategic policy for enacting and implementing biosafety laws. Not a single country in sub-Saharan Africa has enacted any laws for enforcing biosafety regulations. This lack of regulatory implementation means that:

- Companies that want to import and sell GM seed will not be able to do it;
- Applications to field test transgenic materials developed locally or from international sources are not possible;
- Approval for importation of GMOs as commodities, or for research and testing purposes, are delayed;
- There is no mechanism to process requests for authorization to produce or grow GMOs on a large scale for commercial purposes, and
- In some cases, even the movement of GMOs between facilities within a country is restricted.

At first glance, it is hard to understand why no biosafety laws have emerged in Africa, despite considerable international effort to pave the way for biotechnology development in Africa. There have been countless educational seminars, training courses and consultations to increase awareness of the African people about the potential benefits, as well as environmental and food safety concerns associated with biotechnology. Only Kenya, and Egypt have workable drafts of biosafety laws. Nigeria has a draft that has yet to be tested to see if it is workable. But those countries are by far the exception to the general rule.

Why are these efforts so disappointing? In the absence of any coherent national strategy, many of these international efforts to help develop biosafety laws do not address the specific needs of the country. Moreover, many of these efforts have not been aimed at those personnel in the ministries responsible for developing biosafety law. Instead, they are directed more toward institutions that don't have power to do that, such as various local non-governmental institutions.

Why aren't African governments acting decisively to create biosafety laws? In my discussions with many African leaders, I have identified two key factors causing the indecisiveness—a lack of skills in policymaking and a lack of "appropriate human capacity."

The Capacity Crisis Within African Government Institutions

Most officials in ministries responsible for enacting biosafety laws lack the policymaking skills required for drafting coherent, consistent and effective legislation, and pushing those drafts through their legislative branches.

Second, some African officials have not been enthusiastic about enacting biosafety laws because they feel that they don't have enough money or "capacity" to implement biosafety laws effectively. Why bother drawing up biosafety laws that you know you can't really enforce?

Untargeted international assistanceOver the years, developmental assistance provided by international donors has become more directed towards local communities—and less toward nurturing the growth of leadership in African government ministries. Most assistance is not clearly coordinated to target the specific needs of the countries that receive it. The result has been a significant shortage of people in government who have the skills to develop strategy and policy—and push biosafety laws through their legislatures.

It is important to note that, major donors have been shifting their approach toward working directly with local communities, rather than work with government agencies. While there is nothing wrong with working directly with local communities, I feel strongly that this approach should not come at the expense of neglecting key government institutions. No matter how corrupt and mismanaged government agencies may be, we must figure out ways to train government officials in the key leadership skills of policymaking and implementation. The shortage of skilled leaders is hardly helped by the fact that so many skilled Africans who are potential leaders are opting to settle in Europe, the United States, or elsewhere in the developed world.

Rather than despair about the lack of leadership, we have to focus on the positive examples that history provides. During the 1960's, when African nations were becoming independent from Europe, the world community made a concerted effort to support the development of leadership skills among young educated Africans. It is no accident that Kofi Annan, now the secretary-general of the United Nations, is a member of that generation of highly skilled, professional leaders.

Few people now remember that, during the 1960's, the per capita income of Ghana, Secretary General Annan's country of birth, exceeded the per capita income

of countries like Malaysia and South Korea. Since then, African income levels have fallen far behind those of Asia, and the gap in leadership skills provides a key reason for that income gap. The rapid development of Malaysia and South Korea stems, in good measure, from those countries' focus on developing practical skills for formulating and implementing coherent, consistent public policy.

Despite the brain drain, I do not believe that Africa's core problem stems from a shortage of knowledge about biosafety or biotechnology—and related issues. There is still adequate knowledge about biotechnology, especially in some Africa's universities. The main problem is a lack of skills among knowledgeable people responsible for sharing that knowledge with political leadership. There is a widespread failure to leverage knowledge into comprehensive, consistent skills for policymaking and implementation.

For inspiration in Africa, I suggest we study the recent history of Botswana—the southern African nation that now has the highest per-capita foreign-exchange reserves in the world. The secret to Botswana's economic growth isn't the country's great mineral wealth. After all, many African countries have enormous mineral wealth. The key to Botswana's success is that Botswana has successfully nurtured the policymaking and implementation skills of a broad range of leaders in both the public- and private sector.

As President Festus G. Mogae recalled in a recent interview, "When we became independent, we were one of the poorest countries in the world." Later, after diamonds were discovered, Botswana engaged a full range of stakeholders in public policymaking and implementation. "We made sure, we put [mineral revenues] to good use," rather than squander them "on prestige projects." As President Mogae added, "our national motto is "consultation." And through consultations we have been able to build national consensus." These consultations helped "[us] apply aid where it best worked". We tried to learn as much as possible, keeping our limitations in mind". We did not impose or try to impose anything on anyone. Instead, we worked through consultation and persuasion. And those who did not agree with the ruling party were free to express their views."

In short, Botswana's policymaking and implementation are successful because stakeholders have a sense of "ownership" and participation. Botswana controls its development in a selective way that meets its needs.

Poorly Defined Partnerships. In contrast, during our training sessions at GBDI, participants in most countries have voiced concerns that international efforts do not get Africans involved from the very beginning in projects that are supposedly designed to help Africans. Most donors come to Africa with their plans already in place—and just want Africans to join in.

A lack of "appropriate human capacity." My personal experience on this issue is that some of the Africans who usually end up working in international donor projects are interested mostly in a different opportunity than the opportunity to make a difference in their country's development. Consequently, many of the efforts have bypassed the right personnel needed to get the required skills for helping ministries. These problems are widespread and I think most donors are aware of them.

Negative Publicity from Extremist Groups. Finally, another set of factors helps to explain Africa's reluctance—the barrage of negative publicity from extremist groups have attempted to portray GMOs as dangerous—even deadly. These groups have labeled GMOs and the products made from them as the seeds of inequity and ruin. Because of inadequate counterbalance to these extreme groups, it is not surprising that some African governments are swayed by absurd rumors about people who have died from exposure to GMOs. It makes no impact on such leaders to point out that there is no documentary evidence for these assertions.

THE ROLE OF GBDI

Since 1999, when we launched the Global Bioscience Development Institute, I have been able to see first-hand how all these barriers play out, as we provided the practical training leaders need for developing skills in policymaking and capacity building.

Leaders from the following countries have participated in our training: Angola, Benin, Botswana, Burundi, Burkina Faso, Cameroon, Central African Republic, Cote d'Ivoire, Democratic Republic of Congo, Ethiopia, Eritrea, Gabon, Gambia, Ghana, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Nigeria, Niger, Republic of Congo (Brazzaville), Rwanda, Senegal, Seychelles, Sierra Leon, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, and Zimbabwe. Time and again, as these sessions have begun, I have seen and heard skepticism and apprehension about biotechnology in the faces and voices of those leaders. But, as each training session unfolds, I have also watched the skep-

ticism fade away. Invariably, each time we bring key leaders up to speed about these issues, I have seen optimism replace pessimism.

I have learned that when African leaders develop a sense of "ownership" regarding biotechnology, hope replaces despair and apprehension. When African leaders realize that biotechnology isn't something that makes sense only for rich countries, they take an active interest in formulating coherent, sensible policy. And when everyone responsible for biosafety is involved in the policymaking process—in an open exchange of views—the result is a strong consensus or "buy-in" from the community. No community can distrust a technology that it controls in order to meet its own needs.

It's important, to repeat, that many ministries need to be involved, and not just one ministry or one set of leaders. Too often, issues of biotechnology and biosafety development have been left only to the ministry of the environment. Or the perception has been that the private sector has been foisting biotechnology on the local community. At GBDI, our approach is to involve not just the public and private sectors, but every ministry touching on biosafety. This includes the ministries of Environment, Trade, Agriculture, Health, Culture, Justice and Science and Technology. For example, in Nigeria, GBDI's training sessions in Nigeria inspired the Federal Government to bring biotech into the forefront of Nigeria's economic development plan.

RECOMMENDATIONS

Based on my experience, here are my recommendations for overcoming apprehension and lack of understanding among African's leadership:

First, regarding trade between Africa and the United States: There is an urgent need to open American markets to African imports, so that we can reduce Africa's dependence on European markets.

Second, on developing policy and capacity building: Foreign assistance to Africa should be carefully thought out so that it focuses on producing long-term benefits, not short-term emotional satisfaction. Our efforts should involve a concentrated focus on developing key skills that African leaders so urgently need for making coherent strategic plans, and building "capacity" for implementing them effectively.

Developing these skills will not only overcome apprehensions and misunderstandings about biotechnology, it will enable African leaders to develop strategic plans that address their own unique needs, not those of the United States or international donors or multinational manufacturers. Instead of merely reacting passively to the proposals and projects developed by donors and other outside institutions, African leaders will set their own pro-active agenda and plans that focus on their own needs, not the agendas of outside institutions.

We need to get every sort of leader involved—from the public and private sectors; from local communities to every key ministries—like Trade, Agriculture, Health, Culture, Justice and Science and Technology. Otherwise, we risk an incomplete consensus—and resentment among at least some stakeholders.

In Kenya, a partnership between the Kenya Agricultural Research Institute (KARI), Monsanto Corp., and USAID has produced homegrown, genetically modified variety of potatoes—that is now undergoing field trials. In Egypt, a similar partnership between USAID, Monsanto and AGERI (Agricultural Genetic Engineering Research Institute (AGERI), part of the Agricultural Research Center (ARC) of the Ministry of Agriculture & Land of Egypt) has produced homegrown GMOs now undergoing trials.

Even if we overcome much of the distrust and apprehension, our projects won't bear fruit if the wrong people are involved—for the wrong reasons. So we need to give African governments incentives to get the right kinds of their own people involved in their projects.

We need to engage central governments and give them and the private sector a much more essential role, not only in formulating policy but implementing it. We also need to let them share in the rewards for their effective participation. Countries must be required to put on the table a certain percentage of the cost of a project. They should also be held responsible for meeting interim and final goals, as would leadership in the private sector.

In return for sharing these risks, local governments will reap huge benefits. They will have a more active role shaping and implementing the policy—and a strong sense of "ownership" that makes public support and effective implementation that much easier.

China and India

Now, allow me to say a few words about my experience with China and India. As a result of my travel and participation in various biotechnology programs in China and India, I have concluded that both China and India have fully embraced the technology. They see it as the wave of the future. This situation contrasts, of course, with the reluctance and anxiety common in Africa.

In India, for example, a massive initiative from business leaders active in biotechnology persuaded the Indian government to give approval for Bt cotton development. That decision is proving to be very wise because many farmers are already benefiting from Bt cottonseeds. When I was in Bangalore, Karnataka State, to speak at the Bangalore Biotechnology 2002 conference, I discovered that biotech growth is creating a strong infrastructure for economic development in Bangalore area. It seems the biotechnology development witnessed in Karnataka state is being duplicated in many other parts of India.

In China, we are all aware that biotechnology is well accepted by government institutions and the private sector. A recent move by the central government to restrict trade in biotechnology probably has more to do with buying time to catch up and allow their local biotech sector develop without having to compete. However, there are many people who are probably much better qualified than I am to talk about that issue.

Both in India and China, we at GBDI have plans to engage leadership in training programs that provide them with a better understanding of the potential of biotechnology, and strategies for implementing policy effectively.

This July, GBDI, along with the government of Anhui Province in China, will conduct a three-week training program to help Chinese managers and officials develop realistic and sophisticated strategies for expanding sales of natural products, using biotechnology. We expect these sessions to help Chinese leaders expand their business not only throughout China but also with trading partners around the world, including the United States. The training will also offer an opportunity for Chinese managers to link up directly with potential partners, affiliates and customers around the world.

In India, we are planning a similar program in partnership with the Department of Biotechnology, in the Ministry of Science and Technology of India. In the future, I would be happy to report to you on the results of our efforts.

Summing up, permit me to review a few important themes:

First, I feel strongly that biotechnology can have a bright future in Africa. How bright that future becomes will depend on how effectively leadership in Africa acquires the skills it needs to write effective, coherent policy—and build support for it among all stakeholders.

Africa will realize its great promise in biotechnology only if all stakeholders take an active role in formulating and implementing policy. Moreover, Africa will have to become a full partner with international donors. Only then will anticipation replace reluctance—and a sense of "ownership" replace alienation.

Finally, prospects for expanding trade ties between the United States and Africa in GMOs and other products of biotechnology are also bright, if we take a patient, long-term approach to building appropriate skills. When Africa acquires the skills it needs to create and implement biosafety strategy, Africa will be drawn inevitably into closer trading relationships with the United States.

Developing the rights skills in the right people may be a slow process, but it is a process that will have self-sustaining results—much like well-balanced, sustainable economic growth. There are no easy short cuts, or quick fixes.

In short, the United States and Africa share a common interest in the long-term development of biotechnology, and we will share equally in its progress if we work together to focus on our common strategic goals.

Statement of Michael W. Deegan

Mr. Chairman, thank you for inviting me to testify on the important subject of how genetically modified organisms impact the implementation of U.S. food aid programs. As a private voluntary organization (PVO) implementing programs on behalf of both USAID and USDA, ACDI/VOCA finds that controversy over this issue has become a significant impediment to food security in low-income food-deficit countries.

Two years ago, my organization surveyed U.S. Government officials, international organizations, private sector representatives and other PVOs to determine whether GMO issues played a significant role in food aid program implementation. As of a

year ago, when we last updated the survey, we concluded that the issue did not pose a significant problem despite a number of instances where concerns about GMOs had been raised.

As we now prepare a second update of the paper, it is clear that GMO issues have become much more prominent. This can be attributed to a variety of factors:

• Continuing efforts of advocacy groups to curtail GMO use, most prominently in Europe;

• Increased media attention to the issue;

• Continuing resistance from the European Union to importation of new GMO commodities; and

• Increased desire on the part of developing country governments to play a regulatory role.

In 2002, United States food aid shipments reached nearly 4.7 million tons. Of that total, approximately 1.5 million tons were corn, soybeans and related products. That is to say that roughly 35% of U.S. food aid could be considered as having varying degrees of GM content.

The Ramifications of the GMO Issue

Food-insecure people pay the immediate price, in the form of hunger, when U.S. food aid commodities are held up or denied because of GMO issues. But there are several secondary implications as well:

• Operating costs for the PVOs increase as a result of the extra time expended on such issues;

• More expensive commodities often have to be substituted to make up the caloric deficit;

• The potential for a commercial market for U.S. commodities to eventually emerge is lessened due to the tainting of the commodity's image;

• Similarly, the potential for domestic food productivity increases through GMO solutions is reduced; and

• PVOs may incur significant financial risk if they hold title to commodity that has been held up late in the process.

THE INTERNATIONAL RESPONSE

The FAO works with the World Health Organization (WHO) to serve as the secretariat to the Codex Alimentarius Commission. Established in 1962, the Commission operates as a consortium of countries working towards international standards on food safety and acceptability. In 1999 the Commission established an ad hoc Intergovernmental Task Force on Foods Derived from Biotechnologies in which government-designated experts were assigned to develop standards, guidelines and/or recommendations for foods derived from biotechnological methods. The Task Force aims to have its recommended standards on GM foods ready for the Commission's approval sometime this year. However, these standards will not be legally binding. Member governments will continue to have the voluntary responsibility to formulate policies towards these technologies. Currently no international consensus on such food standards exists.

FAO, WFP and WHO issued a joint statement in August 2002 relating to the humanitarian crisis in southern Africa. In it they indicated that the United Nations agencies involved will seek to establish a long-term policy for food aid involving GM foods or foods derived from biotechnology. The statement held that the ultimate responsibility for the acceptance and distribution of food aid containing GMOs rests with the governments concerned, considering all the factors outlined above. The United Nations believes that in the current crisis governments in southern Africa must consider carefully the severe and immediate consequences of limiting the food aid available for millions so desperately in need.

THE U.S. GOVERNMENT POSITION

USDA officials contend that food safety concerns are the same for both traditional and biotech food products. They argue that all biotech developments undergo a rigorous evaluative process and are approved for commercialization based on U.S. laws and regulations which have as their primary goals the health and safety of humans, plants, animals and the environment. Once a plant variety successfully passes U.S. regulatory review, it can be used like any other variety. Foods exported commercially or as food aid by the United States are the same foods as those consumed by Americans every day.

U.S. Government officials do not believe that the U.S. food production and distribution system can reliably separate genetically modified foodstuffs from their non-biotech counterparts. If another country were to demand non-food aid commodities from the United States, our government would respond that any corn or soy-

bean shipment is likely to contain GMOs, that these products have gone through the U.S. regulatory process, and that they are the same foods bought and consumed in the United States.

The U.S. Government has launched biotech education programs in food aid recipient countries in an effort to clarify the U.S. regulatory process for biotech products, to address host country concerns, to correct any misperceptions concerning the health and environmentalimplications of biotech products and to facilitate the development of foreign markets for all U.S. agricultural products.

The Congress, for its part, included a provision in the current farm bill, Section 1543A, authorizing the use of Federal funds by USDA to establish a biotechnology and agricultural trade program. The purpose of the program is "to remove, resolve, or mitigate significant regulatory non-tariff barriers to the export of United States agricultural commodities."

PROBLEMS ENCOUNTERED

Instances of GMO food aid controversy are rapidly accumulating. At a minimum these have generated considerable extra workload for PVOs in implementing programs and have resulted in operational delays. In some cases they have prevented the utilization of the preferred commodity.

ACDI/VOCA in Uganda For example, in 2001, ACDI/VOCA initiated a direct distribution program to provide Corn Soy Blend (CSB) rations to 60,000 people living with HIV/AIDS in Uganda. In early September of that year, American Soybean Association (ASA) soy flour arrived at Entebbe airport and was confiscated by Ugandan customs officials. The Ugandan Government cited concerns that the shipments contained genetically modified (GMO) soy products. During the same period, ACDI/VOCA's P.L. 480 Title II program shipment of CSB arrived in Kampala and was also seized by customs officials citing the same concerns of GMO content. In addition, the packaging did not meet Uganda's National Bureau of Standards (UNBS) labeling requirements for imported pre-packaged foods.

The Ugandan Government requested ACDI/VOCA to provide USG information on GMOs and provide additional commodity information to fulfill its labeling requirements. After the review of the documents provided by USDA, the North American Millers' Association, and the American Soybean Association, as well as testing of the CSB by the Uganda National Council for Science and Technology, the 1500 metric tons (MT) of the impounded commodity (CSB) were released on the condition that all future consignments conform to relevant labeling standards and regulations. ACDI/VOCA and the U.S. Government are now working together to ensure that the Ugandan Government's regulations pertaining to the labeling of imported agricultural products are met on all future consignments.

As of the end of 2001, the Government of Uganda drafted a new biosafety policy and new legislation on biotechnology that proposes strict control of genetic engineering procedures and genetically modified organisms. The drafts have been released to the public for discussions before being submitted to the parliament later in 2003. The proposed policy and legislation both caution that "an appropriate balance should be maintained between biotechnology promotion and regulation."

SOUTHERN AFRICA EMERGENCY RELIEF

Drought in southern Africa has left over 14 million people on the verge of starvation. The looming famine is complicated by the HIV/AIDS pandemic and the collapse of the agricultural infrastructure necessary for the delivery of adequate food supplies and other related services to the region.

In 2002, the U.S. Government facilitated the shipment of food aid to Zambia, Zimbabwe, Malawi, Swaziland, Mozambique, and Lesotho through the World Food Program and PVOs. The delivery of aid faced strong opposition, especially in Zambia and Zimbabwe, because some of the commodities earmarked for food aid have been genetically modified. These governments feared that GMOs, especially corn, through cross-pollination with locally grown crops, could endanger the future of commodity exports to the European market where GMO corn is banned. Specific country information is provided below.

With an HIV/AIDS pandemic and recent severe drought conditions, Zambia faces one of the greatest threats of famine, and has also been at the center of the intense debate over GMOs. In August 2002, the government banned the importation and distribution of all genetically modified foods, including corn, being offered as food aid from the United States. The refusal of the food aid was based on concerns about public health, biosafety and foreign export income. In late October, Zambia received a report from its scientists who had traveled to the United States, Europe, India and South Africa to study the safety of genetically modified food and its approval

process. The report, submitted by Dr. Mwananyanda Mbikusita-Lwewanyika, a biochemist from the National Institute for Scientific and Industrial Research, recommended keeping the ban in place.

The ban has inhibited relief efforts in Zambia and will continue to be a major hurdle in staving off starvation of over 2.9 million Zambians who need 21,000 MT of food aid a month. The distribution of 40,000 MT of corn has already been blocked by the government for fear that farmers would plant the seeds and pollinate organically-grown local corn with unwanted genetic material. In November, the first of 18,000 MT of food aid was loaded into trucks under police guard destined for Malawi. Due to these restrictions, by the end of 2002, food aid distribution was facing massive shortfalls. In early January 2003, the Minister of Science and Technology, Mr. Abel Chambeshi, announced the completion of GMO guidelines which have been submitted to the cabinet for review before being submitted to the parliament. No details of the guidelines have been made public.

As the debate raged in southern Africa, Zimbabwe, the former breadbasket of the region, faced drought and a collapse of the agricultural infrastructure. With half of its 12½ million people facing starvation, the Government of Zimbabwe relaxed its previous hardline stance against GMOs and allowed the introduction of milled corn from the United States. Milled corn helped alleviate starvation without endangering the organically-grown local corn crop, thus safeguarding Zimbabwe's potential for export to the European market. Concurrently, the Government of Zimbabwe is working to develop a biosafety screening system for GM crops for human and farm animal consumption.

ADRA in BoliviaIn 2001, ADRA had problems with food aid it was trying to monetize in Bolivia. According to ADRA, the Bolivian Government banned all food aid and food imports from the United States during March and April 2001 due to concerns about the safety of GM foods. ADRA, CARE, and Food for the Hungry International were all impacted significantly by Bolivia's ban on U.S. food aid. During the ban, ADRA's last commodity shipment of wheat flour was in port in Matarani, Peru, ready for monetization in Bolivia. ADRA was forced to store the flour in warehouses for seven weeks. To resolve the issue, ADRA's Bolivian field officers reminded Bolivian officials of the country's pressing need for food aid and suggested that the government's first priority was meeting its population's food demands. The government eventually lifted the ban.

CARE in India

In October 1999, CARE-USA conducted an emergency food aid relief program in Orissa, India, where a cyclone had struck. CARE's emergency food assistance, which included corn-soy blend containing GMOs, triggered a media outcry driven by anti-GMO activists. It was claimed that the United States had dumped GM commodities on developing countries in the form of food aid because the European and Japanese markets would not buy them. Greenpeace claimed it was illegal to bring GM CSB into India and charged CARE with distributing tainted food to relief recipients.

CARE responded to the concerns by obtaining a document from USDA noting that all U.S. corn and soybeans are likely to contain GMOs, and that the foods were safe and were widely consumed in the United States and Europe. The Government of India (GOI) appeared to accept this reassurance and thanked CARE for its emergency relief efforts. The GOI indicated its appreciation of and support for U.S. food aid programs. However, the net effect of the CSB import ban was to reduce the CARE program by approximately two-thirds.

The GOI has recently reaffirmed its position not to allow CSB into the country until specific issues are addressed, including the need for the USG to provide certifications for each shipment of CSB that no Starlink corn is included. CARE India has said they will not spend more time on this issue. Even if the USG and GOI reach some agreement (which CARE does not believe to be likely for a long time, if at all) and CSB can come in, CARE India will not request the reimportation of the commodity.

CARE at this time, will continue to program CSB in countries where local governments permit it, but will also respect the decisions of governments that may choose to prohibit it.

• PVO Views

ACDI/VOCA has taken the position with respect to U.S. food aid programs and biotechnology that:

• Programs are acceptable that utilize genetically modified commodities provided that the commodities have been demonstrated to be safe through an independent, transparent and scientifically-based approval system.

• Restricting genetically modified commodities and products from food aid programs would be extremely detrimental to addressing immediate food needs around the world.
• It is the responsibility of the U.S. Government to address issues raised by recipient governments as to the acceptability of genetically modified food aid commodities. ACDI/VOCA can play a facilitating role in communicating the recipient government's concern and providing supporting documentation.

Most PVOs have taken somewhat less of an advocacy role with respect to this issue, opting for a neutral position. Most PVOs continue to express a desire for more knowledge on the safety of GMOs before reaching definitive conclusions.

THE U.S. GOVERNMENT/PVO INTERFACE

Last September key USAID/Agriculture and USDA/FAS biotech staff met with members of the Coalition on Food Aid to discuss food aid biotech issues. PVOs indicated that some form of certification from the USG is needed that could be used by PVOs for commodities with GMO content. USAID and USDA representatives responded that, although a specific certificatemay not be feasible, they agreed that PVOs should not have the burden of gathering all the information and trying to make the case to foreign countries. It was observed that this could unintentionally set inappropriate precedents for what types of information a foreigngovernment will expect related to GMO commodities.

It was agreed at the meeting that USDA and USAID will work with PVOs to:

identify a systematic approach for providing information to foreign countries about food aid from GMO commodities; help PVOs better understand the bilateral and multilateral agreements and negotiations related to biological and health safety; and help PVOs understand what the USG can do, and is doing, to help developing countries that are reviewing GMO commodities or are attempting to set up systems to review such products.

As a first step, the USG representatives agreed to contact the cognizant USDA and USAID biotech staff and designated FAS/Export Credits and FFP officers who handle these issues to set a "strategy" meeting where a smaller group of PVOs, USDA, USAID, and perhaps USTR and agricultural groups can discuss the scope of work for these efforts.

Unfortunately, there is little information available on what steps have been taken, if any, to pursue the agreed upon agenda.

WHAT CAN BE DONE TO IMPROVE THE SITUATION?

If optimal use is to be made of U.S. food aid in promoting food security around the world, greater effort needs to be made to minimize the kinds of problems that have occurred in places like Uganda, Zimbabwe, Zambia, Bolivia and India. To do so, the following actions are recommended:
• The administration should accelerate its implementation of the points agreed to in consultation with PVOs last fall;
• USDA should develop and publicize its plan for implementing section 1543–A of the farm bill.

STATEMENT OF LEON CORZINE

Good morning. Chairman Goodlatte, Ranking Member Stenholm and members of the Committee, my name is Leon Corzine and I am a fifth generation farmer from Assumption, Illinois. I am a board member of the National Corn Growers Association (NCGA) and Chairman of the NCGA's Biotechnology Working Group. I would like to thank the Subcommittee for giving me the opportunity to testify and speak today regarding artificial barriers to trade and food aid in agricultural products produced through biotechnology. Today's hearing is very timely and I commend the chairman and the Committee for convening today's hearing.

The National Corn Growers Association (NCGA) is an organization founded in 1957 and represents more than 32,000 dues-paying corn growers from 48 states. The Association also represents the interests of more than 300,000 farmers who contribute to corn checkoff programs in 19 States.

The National Corn Growers Association's mission is to create and increase opportunities for corn growers in a changing world and to enhance corn's profitability and usage across this country. Biotechnology and trade remain vital to the future of corn growers as we search for new markets and provide grain that is more abundant and of better quality.

Biotechnology offers corn growers improved efficiencies and potential profits when managed wisely and with regulatory oversight based on sound science. The introduction of new varieties and its proliferation across the corn-belt is redefining current systems of price discovery, consumer information, health regulation and trade management.

The NCGA believes consumer acceptance and confidence in our regulatory agencies is vital to the success of this technology. As producers, corn growers have to be mindful of our customers and ensure there is open communication with grain handlers, millers, processors and food retailers across the country. Our association works closely with our partners in the food chain continuing an open dialogue to head off any problem before it occurs. We also believe consumer acceptance of biotechnology will increase with the dissemination of science-based information. Responsible and accountable management by biotechnology providers, producers, suppliers, and grain merchandisers is imperative. Copies of NCGA's policies regarding biotechnology are attached.

As you know, corn is the largest crop in the United States, with over 79 million acres planted last year, producing 9 billion bushels of grain. Corn acreage is likely to increase this year with over one third devoted to varieties derived from biotechnology. While corn producers across the country already understand the benefits of biotechnology, farmers around the globe are beginning to realize the true potential of this exciting technology.

According to a new report from the non-profit International Service for the Acquisition of Agri-biotech Applications (ISAAA), the amount of land planted worldwide with biotech crops increased by 12 percent in 2002. This is the sixth straight year that global farmers have adopted biotech crops at a double-digit pace. While the majority of the global area planted to biotech crops is in the United States, accounting for 66 percent of global plantings, the adoption of biotech crops in 2002 was more than twice as fast in developing countries as it was in developed countries.

In the United States, consumer support for food biotechnology remains high. According to the International Food Information Council (IFIC) nearly three quarters (71 percent) of the U.S. population said they would be likely to buy produce that had been enhanced through biotechnology to be protected from insect damage and require fewer pesticide applications. In contrast, a majority of Europeans do not support GM foods while support for GM crops is lukewarm. Foods and to a lesser extent crops, are judged not to be useful and to be risky for society. Overall support for GM foods is seen in only four countries—Spain, Portugal, Ireland and Finland.

Corn growers and farmers across the country are facing various challenges in the international marketplace and the progress resulting from biotechnology is complicating the international grain trade. I can personally attest to the importance of this issue. The region I farm is impacted significantly by trade barriers and the use of new technology is restricted since Illinois exports a significant share of its corn crop.

International acceptance to biotechnology is the largest challenge facing corn growers. One out of every five rows of U.S. corn is exported, and exports of value-added corn and co-products like corn gluten add to the importance of foreign markets for U.S. corn producers. Last year we exported over $4½ billion of corn, and over a billion dollars of value-added processed corn products. This pressure will increase with the release of two new events this year.

The slow acceptance of biotechnology in the international marketplace also threatens to disrupt traditional trade relationships. In the world market, two out of every three bushels of corn originate in the United States and we account for more than 40 percent of the total production worldwide. Despite international opposition, biotech corn is present everywhere and with additional biotech acres planted annually, requirements like labeling and segregation will be difficult and costly. For example, on my farm we identity preserve using global positioning and on farm storage to grow specialty crops.

Global Outlook

Much has changed in the world market for corn in the seven years since the introduction of biotech corn. The quantity of U.S. corn exports has declined from 52.3 million tons to 47.3 million tons and their value has dropped from $8.5 billion to $4.9 billion. Numerous factors have influenced these trade patterns. The short crops and high prices of the mid 1990's boosted the value of corn exports well above traditional levels. The decline of the Former Soviet Union as a corn market and the rise of Mexico to our second largest market shifted trade patterns. The attached graph shows the relative changes in regional markets for corn over the past decade.

To date, trade problems with biotechnology have had moderate influence on the overall U.S. export situation for corn. However, in some important markets the influence has been dramatic, and we anticipate that the next few years may bring in-

creasing pressures on U.S. corn exports as more countries introduce biotechnology labeling and approval systems and move to implement the Cartagena Protocol on Biosafety (BSP). I would like to spend a few minutes bringing you up to date on current and future biotechnology issues that may affect our major corn markets.

ASIA

Asia, led by Japan, remains our number one regional market for U.S. corn. Exports to the area have remained at about $2.2 billion over the past decade. However, there have been some important shifts in the distribution of the market, some attributable to difficulties with biotechnology regulation.

Japan is the largest customer of U.S. corn and has adopted a pragmatic approach to biotechnology. While they have instituted a program of biotechnology labeling, they have limited it to a small segment of foods and have included reasonable commercial tolerances. Japan's safety assessment system has operated in a transparent and reasonably predictable manner. Our major issue with Japan was the inadvertent co-mingling of StarLink corn not approved for use in Japan in U.S. commodity shipments in 2000. This caused a sharp drop in the Japanese market. While that market returned to previous levels, the discovery of StarLink in a U.S. corn shipment last December has renewed the concern of Japanese corn buyers. Japan has a strong preference for the U.S. over other suppliers for quality and reliability reasons. The feed corn market in Japan remains firmly committed to U.S. supplies, but food corn buyers could again change suppliers if there are further findings of StarLink corn in U.S. food corn shipments.

One issue on the horizon in Japan is their introduction of a new 1 percent tolerance for unapproved varieties in corn destined for animal feed. Since Japan has usually approved all the commercial varieties planted in the United States this may not be much of an issue in the commercial market, but it could be a concern if there is any change in the timeliness of their approval system.

Our second major market in Asia, Taiwan, has generally followed the Japanese model of regulation. While exports to Taiwan are off about 20 percent over the past decade, it is difficult to separate any market effect of biotechnology from the availability of subsidized corn from China in the region.

A decade ago Korea was a major U.S. corn market. However, our market in Korea dropped from nearly $300 million in 2001 to $85 million in 2002, coincident with the introduction of strict biotechnology labeling regulations in Korea in 2001. Korea's labeling regulations apply both to unprocessed and processed foods. While on the surface they appear similar to the regulations in Japan, including thresholds and provisions that exempt foods from labeling if there is no analytical evidence of the use of biotechnology, Korean authorities have enforced these regulations in a manner that has caused buyers to seek other suppliers and has interrupted the commodity trade and the processed food trade as well.

The big question on biotechnology in Asia is China. We have other, more pressing, issues with the corn trade with China at the moment, specifically their failure to implement tariff-rate quotas for import of corn in a commercially viable manner and continued use of export subsidies. However, when these problems are resolved, China holds long-term promise as a market for U.S. corn.

Despite this, trade disruptions experienced in the soybean market could easily occur with corn as well. China's system of biotechnology approval requires layer after layer of redundant and unnecessary data submission and field testing within China. We do not dispute China's right to operate a robust regulatory system. However, the manner in which their requirements have been implemented is anything but transparent, and changes from day to day. In addition, as many as five different Chinese ministries are regulating biotechnology, and often their statements and requirements are in conflict with one another and leave traders entirely in the dark about the procedures they must follow.

NORTH AMERICA

The big success story for U.S. corn exports over the past decade has been the emergence of Mexico as our second largest market since adoption of the North American Free Trade Agreement (NAFTA). Mexico has grown from a $100 million market in 1992 to a $600 million market today. While we have not experienced trade difficulties with Mexico due to of biotechnology, we should recognize Mexico is sensitive to potential environmental issues because of its position as a center of origin for corn. The Mexican government has recently announced a new program for safety and environmental evaluation of biotechnology products and we need to be sure this process is grounded in science and follows internationally accepted norms. In addition, some elements in Mexico have attempted to use the issue of bio-

technology as part of a much larger movement to retreat from the trade commitments of the NAFTA . The United States should be firm in its stance and insist technical issues not be commingled with economic issues.

AFRICA AND THE MIDDLE EAST

Africa and the Middle East have also been growth areas for U.S. corn over the past decade, with exports generally doubling in volume and value. The primary market influenced by biotechnology is in the Persian Gulf States where there is concern that biotechnology could permit introduction of swine genes into food products. While our whole corn exports to this region continue to grow, exports of corn oil to the Middle East have declined $80 million since the introduction of biotechnology, largely driven by policies in Saudi Arabia. They and other Gulf nations have introduced labeling regulations that are causing difficulties for our food processing customers, and there are unconfirmed reports of a possible Saudi ban on imports of meat and poultry products fed genetically modified grains that could affect raw grain exports.

Sub-Saharan Africa is not a major area of commercial corn sales, but we are concerned about the recent controversy in the region concerning the acceptability of U.S. corn in development and emergency food relief programs. There has been a concerted campaign by some international non-governmental organizations based in Europe to convince hungry African countries that food that has been safely grown and consumed for years in the United States is unsafe, and if they permit their citizens to consume this food aid they will somehow loose export markets to Europe. Several hundred thousand tons of processed U.S. corn products and about four hundred thousand tons of corn go to these programs each year. While we are concerned about the potential disruption in this outlet for U.S. corn, we are more concerned at the prospect for scare mongering about the safety of U.S. corn affecting the livelihood of citizens in the region.

SOUTH AND CENTRAL AMERICA AND THE CARIBBEAN

Governments across the Americas are generally receptive to the new technologies being adopted by U.S. farmers, with the major exception of Brazil. Farmers in Argentina are second only to those in the United States in their use of biotechnology varieties in both corn and soybeans. As our colleague from the American Soybean Association (ASA) will note, the legal situation in Brazil regarding approval of biotechnology crops has created much difficulty with widespread plantings of soy varieties that have not been approved within that country. Our larger concern in the South American region is whether countries in this region will implement the Biosafety Protocol in a way that does not disrupt trade.

EUROPE

Europe is the clear exception in the corn trade situation. The corn trade with Europe, worth over $300 million per year in the mid–1990's, has disappeared since 1998 due to the EU's inability to operate its own regulatory process. And, regulations soon to be adopted in Europe could continue this situation for many years. Even with resumption of a predictable approval system in Europe, pending regulations on labeling of foods derived from biotechnology and on product tracing, will likely make it extremely difficult for European food companies to use either U.S. corn or many of the food products made from corn. While we have lost the whole corn market in Europe, we continue to ship over half a billion dollars of corn oil and processed corn feed to Europe. Depending on how the new regulations are implemented this market could be at risk as well.

A decade ago the former Soviet Union (FSU) was a major outlet for U.S. corn, but economic circumstances have caused that market to nearly disappear. However, should the FSU re-emerge as a market for U.S. grain, pending regulations there could prove difficult as well. As with China, Russia is in the process of implementing new approval and labeling regulations. The regulations are under constant revision and re-interpretation, and grain exporters are uncertain regarding future requirements.

INTERNATIONAL REGULATION

What is clear from this review of world regulation of biotechnology and the corn trade is that there is little consistency from region to region or from country to country in how our products are treated in the world market. More than anything, we need to find some way to achieve international harmonization, or at a minimum mu-

tual recognition, of regulatory systems for biotechnology in order to continue our trade in the future.

The Cartegena Protocol on Biosafety will soon be a reality as the required 50 countries ratify this treaty. While the Protocol is ostensibly an environmental treaty, several provisions, including those requiring notification of shipments of genetically modified grains, have the potential for trade disruption. Implementation of the notification provisions of the protocol will largely be the responsibility of individual countries. We are concerned that grain shippers will be facing yet another set of disparate and conflicting requirements for compliance with the Protocol and urge the U.S. Government to do all it can to seek reasonable implementation of this treaty.

The U.N.-sponsored Codex Alimentarius Commission is close to completing its work on an international standard on risk assessment principles for foods derived from biotechnology. These principles should be adopted this summer, and the United States should insist that countries that are instituting new approval regulations for biotechnology products follow the science-based evaluation system endorsed by this group. Since the WTO's Sanitary and Phytosanitary Agreement recognize the Codex Commission's rules as acceptable standards, we should insist that countries follow these rules when evaluating new biotechnology crop varieties.

The detractors of biotechnology want to hold onto an aesthetic of farming that no longer exists. With over 6 billion inhabitants, the Earth needs biotechnology to feed developed and developing nations alike. Without a doubt, the images used by Greenpeace activists use are frightening. Even more frightening is the potential result these irresponsible actions will have on starving populations. If we adhered to the internationally politically correct standard of farming, the level of starvation in Sub-Saharan Africa and other parts of the world would be much worse.

For example, the Europeans convinced Africa, a continent riddled with starvation, that biotech corn is poisonous. Guards were blocking the U.S. food aid corn from release. The people were so hungry that they broke into the warehouses and took the corn. Government officials from Africa truly believe that they are protecting their citizens from a danger and that biotechnology is dangerous.

However, researching the issue a little more in-depth, one would find that crops derived from biotechnology are in most instances, safer that their conventional counterpart. When tariffs and safeguard actions are no longer available, sanitary and phytosanitary barriers are the choice du jour. If we allow this trend to continue we will damage all aspects of trade, for exporters and importers alike.

Competition for international markets will be fierce. The United States is already feeling the pressure applied by competitors like Argentina and China. In fact, USDA's corn export estimate for 2002–03 was lowered 75 million bushels to 1,750 million, the lowest export level since 1997–98. This raised ending stocks and led to reductions in both corn and sorghum price estimates.

Having described the challenges facing corn growers and agriculture, I do not recommend retreat in the face of these challenges. Our future as agricultural producers is linked to biotechnology and trade. The United States Government and organizations like NCGA need to promote the benefits of biotechnology while backing up those benefits with scientific analyses that will gain and sustain the confidence of even the most skeptical individual. This is a daunting challenge but one we stand ready to confront.

We look forward working with the Committee on this and other issues of importance in the future. I thank you again for the opportunity to address the Committee. I welcome your questions.

NCGA Position Paper

Title: BiotechnologyDate: 3/03Position Number: I-A–1Expires: 3/04

Background: The development of biotechnology offers great promise for society. Biotechnology offers corn growers improved efficiencies and potential profits when managed wisely and with regulatory oversight based on sound science. The proliferation of biotech corn is redefining current systems of price discovery, consumer information, health regulation and trade management. Worldwide consumer acceptance of biotechnology will increase with the dissemination of science-based information. Responsible and accountable management by biotechnology providers, producers, suppliers, and grain merchandisers is imperative. We must address our customers' concerns and protect our traditional markets.

Resolution/position:

1. Support the positive contributions of biotechnology as it relates to human health, the environment, grain quality, and production benefits.

2. Support trade negotiations including the specific objective of harmonization or mutual acceptance of biotech agricultural products.

3. Support the development of internationally accepted, science-based tolerance standards. Encourage World Trade Organization action against the European Union for their illegal moratorium on the approval process of biotech corn.

4. Support the commercial release of biotech corn hybrids or products that have been fully approved by the relevant U.S. and Japanese regulatory agencies and for which the product registrant is aggressively pursuing approval in every country or bloc that requires approval prior to importation of corn, corn products, or food containing corn ingredients. Recognizing the importance of every customer of U.S. corn and corn products, NCGA will insist that every product registrant conducts due diligence in bringing products to market in a manner that does not disrupt domestic or international trade and will initiate discussions with biotech providers and end users to develop a certified marketing system that assures all events and products will reach appropriate markets.

5. Marketing of corn by the seed industry that does not have worldwide approval must be focused in areas that do not jeopardize the export of commodity corn and commodity products.

• Encourage improvement of existing grain channeling systems, including training.

6. Support the release of biotech corn that is intended for a specific end use and that has limited regulatory approval only through closed marketing systems or carefully conceived identity preservation systems that secure our ability to market corn and corn products worldwide.

7. Request that biotechnology providers assure the availability of accurate, affordable, timely tests to detect the presence of the regulated trait. Tests should be available prior to the release of new products.

8. Continue efforts to advise growers to insist that 2003 corn seed has been tested for the presence of Cry9C according to the U.S. Department of Agriculture (USDA) recommended testing protocol.

9. Support establishing a science-based tolerance for commingled StarLink corn.

10. Support widespread promulgation by seed retailers of hybrid-specific export approval status to enable growers to immediately determine which hybrids are currently approved and which are not.

11. Request the seed industry to clearly label and identify the approval status of all varieties and to augment this effort with an aggressive communications program targeting grower customers.

12. Support Food and Drug Administration's efforts to provide guidance for voluntary labeling that indicates whether foods have or have not been developed using bioengineering to identify attributes that are important to consumers in a manner that is truthful and not misleading and that provides for reasonable tolerances.

13. Support Grain Inspection, Packers and Stockyards Administration (GIPSA) efforts to develop merchandising standards for goods that do not contain biotech corn.

14. Encourage the mediation and resolution of biotech issues in a manner, which limits disruption of domestic and international corn marketing.

15. Encourage the Environmental Protection Agency (EPA), registrants and the research community to work closely with producers to develop resistance management strategies that are workable for producers.

16. Require the seed industry to aggressively promote Insect Resistance Management (IRM) in their seed sales strategy.

17. Encourage biotech providers to avoid the use of antibiotic markers that unnecessarily raise consumer concerns.

18. Support the establishment of a publicly-funded research center at a land grantinstitution to disseminate information, science, etc. about biotech.

19. Technology agreements should indemnify producers from liability once they follow regulations and guidelines provided by the biotech provider and seed companies.

NCGA further encourages non-commodity corn that does not have full feed and food approval or tolerance be grown using science-based isolation and containment requirements away from corn grown for food or feed use.

20. Seed companies to include on the seed tag the percentage of biotech seed in the unit.

21. Encourage technology providers to fully engage all regulatory options to reduce possible risk to commodity corn.

NCGA PositionTitle: Novel TraitsDate: 3/03Position Number: I-A–2Expires: 7/03

Background: We believe that there is long-term opportunity for farmers to grow valueadded products derived from biotechnology and extracted from plants. Pursuit of this new technology platform holds great promise for society. The National Corn Growers Association will continue to work responsibly to position growers to capture value from these new products that ensure the safety of the food supply.

Some biotechnology products require extensive management. Trained and certified growers have the skills and ability necessary to produce these crops with proper audits. Containment and isolation of biotechnology products are critical issues that must be resolved in order to protect traditional markets, and realize the promise of this technology. Each product should be grown and handled differently based on a scientific risk assessment and therefore each product should have specific requirements for regulatory approval.

We urge that Federal policy not force abandonment of the process that has already been made to develop novel products in corn. Most importantly, we urge that Federal policy not prevent or exclude the opportunity to develop and grow these new products.

1. Promote research that leads to education of the general public on the benefits to the consumer of plant derived biologics.

2. With regard to field production of plant derived biologics (PDBs) such as corn containing pharmaceuticals and industrial enzymes, NCGA requests inclusion of the following recommendations to the Biotech Regulatory services of APHIS:

Isolation from commodity corn through the use of:

Non transgenic pollen or male sterile corn

Dedicated systems of production

Third party verification

A process that ensures plant containing an unapproved trait be 100 percent detassled

A fallow system where appropriate A grower training, testing and auditing program to implement standard operating procedures

3. Support the establishment of an independently owned and operated biotech "underwriters laboratory" to ensure consumer safety and confidence.

4. Strongly encourage the development of technology protection systems in all pharmaceutical and industrial enzyme corn.

STATEMENT OF BOB STALLMAN

Good morning. I am Bob Stallman, president of the American Farm Bureau Federation, and I am pleased to provide you with our views about the impacts of artificial barriers to trade and food aid in agricultural products produced through biotechnology.

Gaining access to international markets for products of agricultural biotechnology is one of AFBF'S priority issues. The promise of this new technology to farmers and ranchers, and to people throughout the world, has only begun to be realized. The opportunities of this new technology to improve agricultural productivity, to improve human health and nutrition, and to improve the world's environment are endless.

AFBF believes any trade barrier erected against food or feed products of agricultural biotechnology that has as its basis the protection of human, animal or environmental health is an artificial barrier. AFBF has yet to discover any peer-reviewed scientific risk assessment that concludes that products of agricultural biotechnology intended for food use are inherently less safe to humans, animals or the environment than their traditional counterparts. Barriers erected or proposed to be erected that will affect trade and/or use of biotech products are in many international policies including, but not limited to, the convention on biological diversity and its Biosafety Protocol, the codex alimentarius, the international plant protection convention, the WTO negotiations on trade and environment, and in the legislative and regulatory bodies of dozens of countries throughout the world. It would take considerable time to describe each and every situation where the issue is being debated, so I will highlight some that have already had a direct impact on trade.

The most notable artificial barrier to trade in biotech products is the moratorium against new approvals of biotech products in the European Union. Widely agreed by most countries to be WTO inconsistent, the moratorium has cost U.S. growers millions of dollars in lost sales since it went into effect in 1998. AFBF and more than 30 other agricultural organizations have campaigned hard to get the administration to initiate a WTO dispute settlement proceeding against the moratorium. We believe that a WTO decision, which is expected to be in favor of the U.S., is the only reasonable remedy available to U.S. growers to either lift the moratorium or impose retaliatory tariffs on EU products imported in to the U.S.

The EU's proposed solution to its biotech moratorium, the enactment of new rules requiring biotech products to be labeled and traced from farm to fork, are equally inconsistent with the WTO agreement on sanitary and phytosanitary measures (SPS) and the agreement on technical barriers to trade (TBT). A WTO inconsistent solution to a WTO inconsistent problem is not acceptable. Mr. Chairman, this com-

mittee and the administration should not believe that the EU biotech problem will be solved if labeling and traceability rules are enacted and the moratorium is lifted. As proposed, the labeling and traceability rules only make the problem worse by erecting new, unscientific barriers to processed food products in addition to agricultural commodities.

The moratorium and labeling and traceability rules will not be the last artificial barriers to agricultural biotechnology in the EU. There is published evidence that some EU member countries may require additional rules to be enacted to clarify environmental liability of agricultural biotechnology before they will vote to end the moratorium.

The ongoing EU moratorium has also fostered the imposition of artificial barriers to agricultural biotechnology in other countries. Scientists in Africa have angrily denounced the EU for its failure to control the anti-biotech messages of EU-sponsored nongovernmental aid organizations. These organizations have exploited the moratorium as an argument against the development and use of biotech products that would otherwise help to feed undernourished populations and foster much-needed economic development.

In China, agricultural biotechnology is strongly embraced and research is significant. Biotech crops such as cotton, soybeans and corn are produced in substantial quantities. Nevertheless the Chinese government has recently used biotech regulation for the purpose of slowing or halting trade in U.S. soybeans.

The lack of coordination between the different Chinese government agencies having responsibility for biotechnology has exacerbated the problem. This year the Chinese are requiring new field testing of biotech products that have already gained temporary approval to enter the country. The field tests are a surprise addition to those conducted last year. Chinese political leaders recently extended China's temporary biotech permit process through April 2004 to allow time for U.S. firms to conduct the necessary tests and to allow trade to continue. However in 2002, U.S. soybean producers lost more than $200 million while the Chinese developed and implemented their temporary regulatory system.

New laws and regulations affecting products of agricultural biotechnology are being considered in 44 nations that have ratified the convention on biological diversity and its Biosafety Protocol. These nations are attempting to comply with their obligations to this international environmental agreement that directs how member countries must treat living modified organisms. The United States is not a signatory to the convention. However, the terms of the Biosafety Protocol require U.S. shippers of biotech commodities to meet certain conditions before they can be accepted if the receiving country is a signatory to the convention.

Mr. Chairman, winning widespread acceptance of this new technology will be challenging and require considerable persistence. It is very important that this committee strongly support aggressive engagement of U.S. agricultural and food interests with foreign governments and research institutions, with foreign industries and most importantly, with foreign consumers to help them understand the benefits and promises of agricultural biotechnology.

SCIENTISTS IN SUPPORT OF AGRICULTURAL BIOTECHNOLOGY

We, the undersigned members of the scientific community, believe that recombinant DNA techniques constitute powerful and safe means for the modification of organisms and can contribute substantially in enhancing quality of life by improving agriculture, health care, and the environment.

The responsible genetic modification of plants is neither new nor dangerous. Many characteristics, such as pest and disease resistance, have been routinely introduced into crop plants by traditional methods of sexual reproduction or cell culture procedures. The addition of new or different genes into an organism by recombinant DNA techniques does not inherently pose new or heightened risks relative to the modification of organisms by more traditional methods, and the relative safety of marketed products is further ensured by current regulations intended to safeguard the food supply. The novel genetic tools offer greater flexibility and precision in the modification of crop plants.

No food products, whether produced with recombinant DNA techniques or with more traditional methods, are totally without risk. The risks posed by foods are a function of the biological characteristics of those foods and the specific genes that have been used, not of the processes employed in their development. Our goal as scientists is to ensure that any new foods produced from recombinant DNA are as safe or safer than foods already being consumed.

Current methods of regulation and development have worked well. Recombinant DNA techniques have already been used to develop "environmentally-friendly" crop plants with traits that preserve yields and allow farmers to reduce their use of synthetic pesticides and herbicides. The next generation of products promises to provide even greater benefits to consumers, such as enhanced nutrition, healthier oils, enhanced vitamin content, longer shelf-life and improved medicines.

Through judicious deployment, biotechnology can also address environmental degradation, hunger, and poverty in the developing world by providing improved agricultural productivity and greater nutritional security. Scientists at the international agricultural centers, universities, public research institutions, and elsewhere are already experimenting with products intended specifically for use in the developing world.

We hereby express our support for the use of recombinant DNA as a potent tool for the achievement of a productive and sustainable agricultural system. We also urge policy makers to use sound scientific principles in the regulation of products produced with recombinant DNA, and to base evaluations of those products upon the characteristics of those products, rather than on the processes used in their development.

Editor's note: The signatures of the 3,300 scientists, along with their affiliations, are on file with the committee

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STATEMENT BY GARY JOACHIM
BOARD OF DIRECTORS, AMERICAN SOYBEAN ASSOCIATION

before the

COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES

March 26, 2003

Good morning, Mr. Chairman and Members of the Committee. I am Gary Joachim, a soybean and corn farmer from Claremont, Minnesota, and member of the Board of Directors of the American Soybean Association. ASA represents 26,000 producer members on national issues important to all U.S. soybean producers.

We appreciate the invitation to appear before you today to present our views on the impact of issues related to agricultural biotechnology on exports of U.S. soybeans and soybean products. ASA is a strong supporter of biotechnology. We have supported domestic and global policies that encourage its acceptance and growth. At the same time, half of annual U.S. soybean production is exported. As a result, ASA's support for this new technology recognizes the importance of maintaining access to foreign markets.

Background

As you are aware, RoundUp® Ready soybeans were released for commercial production in 1996, after approval in the European Union and Japan. By 2002, 74 percent of the U.S. soybean crop was RoundUp® Ready. However, as questions about biotechnology have been raised overseas, ASA became concerned about the possible disruption of foreign market access resulting from delayed approvals of other new biotech soybean varieties.

In 1997, ASA sent letters asking the major biotech seed companies to not commercialize new biotech soybean varieties until they are approved for import in major foreign markets. In the event a company chooses to go forward with commercialization, ASA asked that they prevent the unapproved-overseas variety from entering export market channels. ASA provided a list of conditions we believe must be met to satisfy this assurance. Finally, ASA asked these companies to document that their production and marketing system meets these closed-loop safeguards.

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As a result of these measures, we are confident that the only biotech soybean entering U.S. export channels is the RoundUp Ready® variety already approved for import in major foreign markets. However, delays in obtaining approvals in major foreign markets – particularly the European Union – is denying U.S. farmers the ability to grow several new biotech soybean varieties approved for U.S. planting. Clearly, the EU's actions are affecting the soybean marketplace.

Market Disruption in the EU

U.S. exports of soybeans and soybean products have been increasingly disrupted by the actions of various foreign governments. Chief among these is the European Union. Despite having approved RoundUp® Ready soybeans in 1996, the EU enacted a mandatory "labeling" law two years later which requires food manufacturers to attach a stigmatizing "GMO label" on any food products containing more than one percent of RoundUp Ready soybeans within that food's soy protein ingredient component fraction. This has caused a large number of food manufacturers who market their products in the EU to switch-away from using U.S.-origin commodity soy protein as an ingredient, or to reformulate their products to exclude any soy ingredients, including even soybean oil.

In addition to the anti-biotech labeling regime already in place in the EU, seven EU Member States have indicated they will refuse to implement biotech approvals in their national regulations until the traceability and labeling regulation is adopted. The European Commission has periodically protested the *de facto* moratorium implied by these policies, but has taken no legal or punitive action to enforce its own policies.

In an effort to rationalize its inconsistent laws and member countries' actions, the EU is preparing to adopt new regulations on mandatory tracing and mandatory labeling of biotech or biotech-derived products that would further restrict access for U.S. soybeans and soybean products. The EU's proposed traceability regulation requires importers and food processors to trace biotech agricultural products and ingredients from farm to dinner table under a paperwork-intensive traceability and segregation regime. Compliance with this traceability regulation by U.S. exporters and food processors would be costly, onerous, and unworkable given the realities of bulk commodity production, marketing, transport, and food processing.

The EU's proposed new traceability and labeling regulation requires that any shipment of agricultural commodities or any food product ingredient containing more than 0.9 percent biotech material be labeled as "containing biotech." Currently there also is discussion to further lower this threshold.

Additionally, the EU's proposed regulation on Novel Food and Feed would be founded on the principle of process-based labeling rather than detection. In other words, it would not matter whether or not a product had any biotech presence; a product would have to be labeled simply if it was "derived" from biotechnology. For example, the labeling requirements would extend to refined soybean oil made from biotech soybeans and processed products containing such soybean oil, even though no modified protein or

DNA is present in refined soybean oil, and it is impossible to scientifically determine if such oil is of "biotech origin" or not. Such a situation would fly in the face of proper scientific and verifiable evaluation and would leave the door wide open to misrepresentation and fraud.

It also should be noted that while soybean oil "derived from" biotech soybeans would have to be labeled, the EU's proposed laws do not extend to biotech processing aids, such as enzymes, amino acids, and vitamins widely used in EU food production. It is perhaps worth noting that nearly all the manufacturers of these biotech processing aids European companies. The EU argues that such biotech products do not constitute a "material" part of the final product.

Our net assessment of the EU's proposals are that they are highly discriminatory and are so commercially infeasible that European food manufacturers and U.S. food manufacturers wanting to market their products in the EU will inevitably continue the trend to reformulate their products using non-U.S. sources of protein and vegetable oil, rather than place a pejorative "GMO/biotech" label on U.S.-origin soy-containing foods or attempt to comply with costly traceability requirements.

We have discussed this situation regularly with Administration officials, who have stated a willingness to consider filing a case with the WTO should the EU go forward. However, we are very concerned that, once in place, these new regulations covering traceability, labeling, and novel food and feed will be extremely difficult to repeal or modify – despite proposals for a two-year review of their "workability." And we are aware that, even should the U.S. win a WTO case, the EU could choose to pay compensation through other EU-U.S. trade concessions that will not restore our lost market share or otherwise indemnify our industry.

Japan -- A Somewhat More Rational Approach

In contrast to the EU, Japan has taken a more rational approach that has not materially impeded access for U.S. soybean and soybean products, at least to date. Japan has enacted a mandatory food GMO-labeling law under which eligibility as a "non-GMO" product is based on commercial "best efforts" to prevent mix-in of biotechnology-derived commodities. Under this regulation, these food products are not required to be labeled as containing biotech material or ingredients. This requirement for commercial "best efforts," coupled with a 5% threshold for the Japanese government to investigate and prosecute labeling violations, has proven to be manageable for most exporters and food manufacturers, and U.S. soy exports to Japan have remained stable during the past five year period.

China – A Moving Target

China has emerged in recent years as the largest foreign market for U.S. soybean exports. While China has also become a significant producer and exporter of biotech cotton and other crops, its regulatory agencies have been highly unpredictable and inconsistent in

establishing and enforcing regulations governing environmental and food safety testing of imported biotech crops and products. The result has been a roller coaster marketplace where U.S. exporters have come within weeks of canceling shipments of U.S. soybeans, and where contracting for new shipments actually came to a halt, for fear they would be rejected upon arrival at Chinese ports due to lack of acceptable documentation.

China's Ministry of Agriculture (MOA) recently extended – for the second time – its deadline for issuing permanent safety certificates for imported RoundUp Ready® soybeans to April 20, 2004. This extension will allow applicable biotech seed companies to complete required field testing and analysis this year, and will enable U.S. soybean exports to reach China unimpeded this Fall and Winter. However, China's MOA is now also demanding nutritional analysis and feeding trials that have already been done in other countries, making their duplication in China unnecessary. On the few occasions that Chinese government officials have publicly spoken about their motivation for such onerous regulation of biotech-containing commodity imports, they have specifically cited the EU "GMO" controversy.

ASA strongly supported China's entry into the WTO, and worked hard with the U.S. Administration to obtain meaningful access for U.S. soybeans and soybean products in China's WTO accession agreement. We are concerned by the willingness of China's regulatory agencies to repeatedly move the regulatory target for approval of RoundUp Ready soybeans. Hopefully, continued vigilance and a demonstration that we will confront all efforts to restrict our market in China will improve this situation. The Administration and Congress must continue to insist that China's political leadership honor and enforce its commitment made to President Bush that access to the Chinese market for U.S. soybean exports will not be restricted.

Developing Countries – The High Price of Precaution

Among developing countries, recipients of U.S. humanitarian food assistance have become caught between their immediate need to alleviate hunger and malnutrition and fear that introducing biotech crops could restrict future access to the EU and other non-biotech markets. A commonly-stated concern of aid-recipient governments is that U.S. food aid provided in the form of viable kernels/beans might get planted by local farmers and mixed in with domestic production, thereby endangering that country's ability to export potentially lucrative "GMO free" products to the EU in the future. USAID and USDA have reluctantly agreed to mandatory processing of U.S.-donated commodities to render them non-viable prior to shipment to Mozambique, Malawi, and Zimbabwe. Other countries are looking at similar restrictions. In addition, the governments of Lesotho and Swaziland have expressed concerns over the environmental safety of U.S. commodity donations.

We all recall the tragedy of Zambia's government recently refusing U.S.-origin food aid, including soy products, due to presumed biotech content. Less well publicized has been the fact that the governments of Zimbabwe, Mozambique, Malawi, Uganda, India, and Ecuador have imposed restrictions that would have hindered the import and distribution

of U.S. soy-containing food aid at one time or another. When investigated, each of these instances of food aid disruption has been shown to arise fundamentally as a result of these nations observing the "GMO controversy" which has become institutionalized in the EU.

A number of other nations that import soybeans and soy products commercially have also been influenced by the European Union's putative concerns with agricultural biotechnology. On several occasions during the last six years, commercial imports of U.S. soybeans or products containing U.S. soy ingredients have been disrupted for a period of time in the countries of China, Saudi Arabia, and Egypt.

The Battle Over International Standards

Coincident with and impacting decisions being made by individual countries on biotech regulatory issues are ongoing negotiations to establish international standards governing trade and labeling of biotech products. These include the Biosafety Protocol, being negotiated under the Convention on Biological Diversity (CBD), and the work of various committees established under the Codex Alimentarius Commission. Adoption of onerous biotech rules under the Protocol or the Codex would provide a sheen of legitimacy to the EU's mandatory traceability and labeling regulations, and potentially encourage or even require other countries to follow suit.

The Biosafety Protocol was completed in January 2000 and signed by more than 130 countries, not including the U.S. Among other purposes, it is intended to regulate international shipments containing any living organisms that could adversely impact the environment in an importing country. By twisting the original intent of the CBD, opponents of agricultural biotechnology were able to insert wording into the Protocol to justify its use as a tool for regulation of international shipments containing biotechnology-derived commodities (called "LMOs" in the Protocol), including establishing approval and labeling requirements for identifying their presence in shipments. The Protocol provides that these LMO-shipment regulation conditions be codified within two years of the Protocol's ratification by a total of 50 countries – expected to occur during mid-2003.

Of particular concern, the Protocol includes a provision referencing the Precautionary Principle, which is being used by the EU to justify the use of unsubstantiated concerns about food safety – rather than science-based determinations – for restricting imports or production of biotech crops and products. Moreover, it is unclear from language in the Protocol whether it would take precedence over provisions in the WTO's Sanitary and Phytosanitary (SPS) Agreement and Agreement on Technical Barriers to Trade (TBT), which require that any WTO member's trade restrictions be based on sound science.

Since the U.S. is not a signatory to the Biosafety Protocol, the Administration has only marginal influence on how its regulatory provisions will be finalized and enforced. Based on the EU's interpretation that the Protocol should take precedence over WTO agreements/rules in governing trade in biotech commodity products, however, developing

countries are already beginning to follow the EU's example. In ASA's view, it is imperative that the U.S. and other concerned biotech-commodity exporting countries identify and develop an internationally-sanctioned alternative to the Biosafety Protocol for regulating biotech commodity trade in the immediate future.

The other multilateral negotiations that are addressing potential regulation of biotech commodity trade are taking place under the auspices of the Codex Alimentarius Commission. The Codex establishes international food safety standards, and is recognized as the official "referee" for cases brought under the WTO. Various Codex committees are dealing with different biotech commodity issues, including potential labeling requirements and whether to accept the Precautionary Principle as justification for restrictions placed on biotech commodity imports.

While the U.S. has full membership rights in Codex committee meetings, there has been an effective standoff between pro- and anti-biotech countries during the past four years. At this time, there is little optimism that these differences will be resolved in a way that allows Codex to protect against unilateral restrictions on biotech trade by a WTO member country, particularly if the Biosafety Protocol sets out guidelines that sanction such practices.

Recommendations

In our view, it is critical that Congress and the Administration develop a comprehensive strategy to improve the current international environment for trade in biotech crops and their products, which has recently become restrictive and is further threatened by the pending codification of more import restrictions in the Biosafety Protocol. This U.S. government strategy should include the following components:

1. The Administration should immediately prepare WTO cases to be filed against the EU's planned traceability and labeling and novel food and feed regulations. Assurance that the U.S. would act forcefully will discourage other countries that are considering following the EU's example.

2. The Administration should continue enlisting the support of other countries for a WTO complaint over the EU's continuing illegal five-year moratorium on biotech approvals that has no scientific justification whatsoever. This issue should not be viewed strictly as U.S.-EU issue since all other countries interested in ensuring that science-based determinations underpin regulatory decisions should join in the complaint. We are gratified by press reports that numerous other countries, including Argentina, Australia, and Canada, among others, may join in the complaint. While it had been hoped that progress was going to be made in lifting the moratorium, EU member states blocking approvals have indicated that they will not give approvals until the EU finalizes and begins implementing the trade-restrictive traceability and labeling and novel food and feed regulations described earlier. The United States and other exporting countries must not accept the

imposition of a set of discriminatory and non-science-based measures by the EU as a condition for ending another non-science-based decision making process.

3. Efforts by the Administration to help developing countries establish a sound scientific and regulatory infrastructure for setting environmental and food safety standards should be immediately and significantly enhanced. This effort should include additional funding for USAID's sustainable development and trade enhancement initiatives, for the education-based programs sponsored by 1890 institutions, and for the Biotechnology in Agricultural Trade (BAT) program authorized in the 2002 Farm Bill. Under the BAT program, private sector organizations and USDA's Foreign Agricultural Service would assist developing countries in establishing science-based regulations for approving production and importation of biotech crops and products.

4. The Administration must immediately identify a viable alternative to the Biosafety Protocol for regulating future trade in biotech crops and their products, and work with other biotech commodity-exporting countries to achieve its rapid adoption. One candidate would be regulation via the International Plant Protection Convention (IPPC), which is recognized under the WTO as the expert reference for standards governing shipments containing live plants, seeds, and plant pests. While IPPC standards could be developed to formally encompass biotech crops, there would need to be a concerted effort to push them forward rapidly to catch up with the timetable for the Biosafety Protocol.

Conclusion

As you can tell from our comments, Mr. Chairman, soybean producers are extremely concerned about the status of international trade in the products of agricultural biotechnology. We are even more concerned that, absent immediate and concerted action by our government and the governments of other biotech-commodity exporting countries, this trade environment could become much worse in the near future. We strongly urge you and this Committee to engage the Administration on this issue as soon as possible. ASA would welcome the opportunity to work closely with you in this endeavor.

Thank you again for inviting us to appear before you today.

TESTIMONY TO THE COMMITTEE ON AGRICULTURE UNITED STATES HOUSE OF REPRESENTATIVES

Calestous Juma
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Kennedy School of Government
Harvard University

March 26, 2003

INTRODUCTION

Biotechnology represents an important set of tools that developing countries could use to raise crop productivity, enhance pest and disease resistance, adapt crops to new or adverse ecological conditions, enhance the nutritional content of foods, reduce post-harvest food losses, and create market for specialty products. Crops of relevance to temperate regions, where their benefits are being documented, have dominated the early stages of the development of biotechnology.[1] It is not unusual for new products and processes to emerge in "centers of technological origin" in the industrialized countries.[2] The issue therefore is identifying the forces that influence the ability of the developing countries to make use of emerging technologies. Current trends in agricultural biotechnology reveal that regulatory uncertainty in international trade has become one of the most critical obstacles to the use of biotechnology to meet the needs of developing countries.

1. BIOTECHNOLOGY AND HUMAN NEEDS

The role of science and technology in globalization is currently at the center of a wide range of international controversies involving pharmaceuticals, foods and software. The debates stem partly from the fact that science and technology is currently viewed in the industrialized countries as a major tool for international competitiveness.[3] But this view

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1. See Gianessi, L., C. Silvers, S. Sankula, J. Carpenter. (2002). *Plant Biotechnology: Current and Potential Impact for Improving Pest Management in US Agriculture: An Analysis of 40 Case Studies*. Washington, DC: National Center for Food and Agricultural Policy; Pray, C., J. Huang, R. Hua, S. Rozelle. (2002). "Five Years of Bt Cotton in China—The Benefits Continue," *Plant Journal*, 31: 423-430.

2. For a review of the history of agricultural biotechnology in the United States, see Juma, C. and Calo, M. (2002). "Government and Technological Innovation: The Case of Agricultural Biotechnology in the United States". In Norberg-Bohm, V. (ed.) *The Role of Government in Technology Innovation: Insights for Government Policy in the Energy Sector*. Cambridge, Massachusetts, USA: Belfer Center for Science and International Affairs, Kennedy School of Government, Harvard University.

3. Archibugi, D., J. Howells, J. Michie. (1999). "Innovation Systems and Policy in a Global Economy", In Archibugi, D., Howells, J. and Michie, J. (eds.), *Innovation Policy in a Global Economy*. Cambridge, UK: Cambridge University Press, pp. 1-15.

has emerged concurrently with growing recognition of the necessity to use emerging technologies to address the needs of the poor in developing countries. Current uses of science and technology apparently conflict with the expectations of a large section of humanity not able to afford basic requirements such as essential medicines, nutritional options and energy.[4]

Social movements and groups around the world are therefore questioning the role of new technologies in meeting the needs of the poor.[5] They contend that new technologies have helped to widen the gap between the rich and the poor within and between nations. Others have gone as far as suggesting that modern technological innovations are a source of social, economic and ecological problems facing developing countries. There is a general mood of suspicion, caution and hostility towards technological innovation worldwide, often fueled by a wide range of social movements.[6] This general questioning of technology is reflected in global debates over access to its products.

The debate over agricultural biotechnology has so far focused on international trade in GM foods.[7] Attempts to resolve the growing concerns through the 1992 United Nations Convention on Biological Diversity (CBD) dealt largely with environmental aspects of living modified organisms (LMOs).[8] Issues related to human health, especially those pertaining to human health, are being negotiated under the Codex Alimentarius Commission administered by the Food and Agriculture Organization and the World Health Organization.[9] Other bodies in the United Nations systems are handling different aspects of the biotechnology debate. For example, the United Nations Commission on Science and Technology for Development is examining issues related to biotechnology capacity building in developing countries. The United Nations Conference on Trade and Development (UNCTAD) is looking into the trade-related aspects of biotechnology.[10] Despite these efforts, the debate has so far focused largely on the risks associated with biotechnology and sidestepped its potential benefits in developing countries.

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4. United Nations Development Programme (2001). *Human Development Report*, Oxford, UK: Oxford University Press.

5. Juma, C. *et al.* (2001). "Global Governance of Technology: Meeting the Needs of Developing Countries", *International Journal of Technology Management*, 22(7/8): 629-655.

6. Social movements working in the field of environment tend to attribute ecological degradation to technological change. Other groups concerned attribute cultural decay to technological change and still others argue that technological change is a source of unemployment. Although there is some truth in these claims, the reality is more complex and defies simplistic attributions of the kinds that dominate popular discourse.

7. Pardo, R., C. Midden, J.D. Miller. (2002). "Attitudes Toward Biotechnology in the European Union", *Journal of Biotechnology*, 98: 9-24; Priest, S.H. (2000). "US Public Opinion Divided Over Biotechnology?" *Nature Biotechnology*, 18(9): 939-942; Macer, D., M.A.C. Ng. (2000). "Changing Attitudes to Biotechnology in Japan", *Nature Biotechnology*, 18(9): 945-947.

8. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted on 20 January 2000 in Montreal and has so far been ratified by over 45 countries and will come into force upon the 50th ratification. Article 1 of the protocol states: "In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

9. The commission was set up in 1961 to administer food safety and quality standards.

10. See, for example, Zarrilli, S. (2000). *International Trade in Genetically Modified Organisms and Multilateral Negotiations: A New Dilemma for Developing Countries*. Geneva: United Nations Conference on Trade and Development.

Ironically, initial policy discussions over biotechnology in the late 1980s focused largely on its potential applications to meeting the needs of developing countries.[11] Governments negotiated and signed the CBD based on detailed consideration of potential role of biotechnology in development. Article 16(1) of the Convention on Biological Diversity provides the basis for international cooperation in the field of biotechnology:

> "Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment."

Indeed, developing countries argued that they could use their biological resources to create new industries using the emerging technology.

In addition to the CBD, the role of biotechnology in development is clearly articulated in Chapter 16 of Agenda 21, the program of work of the 1992 United Nations Conference on Environment and Development. According to Chapter 16 of Agenda 21, biotechnology:

> "promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes. Biotechnology also offers new opportunities for global partnerships, especially between the countries rich in biological resources (which include genetic resources) but lacking the expertise and investments needed to apply such resources through biotechnology and the countries that have developed the technological expertise to transform biological resources so that they serve the needs of sustainable development. Biotechnology can assist in the conservation of those resources through, for example, ex situ techniques."

The promises of these international commitments remain unrealized, largely because biotechnology has increasingly been defined in terms of its risks and little consideration has so far been given to finding mechanisms that offer a balanced assessment of its potential.[12] This has partly been because of the absence in most developing countries of science and technology policies that clearly articulate the importance of biotechnology as an essential aspect of development.[13] Enterprises in developed countries have in turn been slow to engage in technological partnerships in developing countries because of concern

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11. Juma, C. (1989). *The Gene Hunters: Biotechnology and the Scramble for Seeds.* Princeton, New Jersey, USA: Princeton University Press.
12. Juma, C. (2000). *Science, Technology and Economic Growth: Africa's Biopolicy in the 21st Century.* Tokyo: United Nations University Press.
13. Consequently, international organizations such as the United Nations are only starting to explore the role of science and technology in international development. See, for example, National Research Council (2002). *Knowledge and Diplomacy: Science Advice in the United Nations System*, National Academy of Sciences, Washington, DC.

over the lack of a policy environment that supports the use of emerging technologies.[14] Efforts to place biotechnology in a risk frame have gone hand in hand with concerns over globalization.[15] In other words, trade and technological competition have provided the context in which international debates over biotechnology need to be examined.[16]

It is therefore not a surprise that the first international regime regulating biotechnology—the Cartagena Protocol on Biosafety—deals mainly with trans-boundary movement of LMOs, which is a euphemism for "international trade".[17] Calling for the recognition of the trade-related aspects of these debates does not in any way seek to diminish the importance of environmental and human health concerns. These are indeed critical and need to be addressed in their own right and should be taken seriously.[18] But focusing only on these issues mystifies more fundamental underpinnings of the debate and is unlikely to resolve the issues.

The rules and decision procedures set out under the Cartagena Protocol are designed to regulate international trade and have inspired a wide range of analyses that examine its relationship with the World Trade Organization (WTO).[19] Follow-up negotiations on international regulation of biotechnology now focus on issues such as labeling and traceability, which are also trade-related issues.

Some consumers in industrialized countries continue to express skepticism towards transgenic foods. This is partly because they have a wide range of foods from which to make the necessary choices. They therefore question the need to use new technologies to make incremental changes in their foods without offering tangible benefits, especially those that help to improve human welfare. Indeed, industrialized countries already face challenges associated with excessive production of food. Many of these countries have put in place policies that seek to link food production with environmental conservation.

Industry in the developed countries is looking into ways to producing foods that are relevant to the consumer. Fields such as 'nutraceuticals' and 'functional foods' are emerging as a response to the growing concern among consumers about their health and well being in general. The success of such investments is still in doubt but it is evident that the concerns in industrialized countries stem from the view that meeting food

14. Rausser, G., Simon, L. and Ameden, H. (2000). "Public-Private Alliances in Biotechnology: Can They Narrow the Knowledge Gaps Between Rich and Poor?" *Food Policy*, 25(4): 499-513.
15. Paarlberg, R. (2000). "The Global Food Fight", *Foreign Affairs*, 79(3): 24-38.
16. Sharp, M. (2000). "The Science of Nations: European Multinationals and American Biotechnology", *International Journal of Biotechnology*, 1(1): 132-151; Bijman, J. and Joly, P.-B. (2001). "Innovation Challenges for the European Agbiotech Industry", *AgbioForum*, 4(1): 4-13.
17. Cors, T. (2002). "Biosafety and International Trade: Conflict of Convergence?" *International Journal of Biotechnology*, 2(1/2/3): 27-43.
18. National Research Council (2002). *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation*. Washington, DC: National Academy Press; Wolfenbarger, L. and Phifer, P. (2000). "The Ecological Risks and Benefits of Genetically Engineered Plants", *Science*, 290: 2088-2093.
19. Article 2(4) of the Cartagena Protocol calls for consistency between the protocol and other international treaties: "Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law."

security is no longer the concern of consumers. Much of the consumer interest is shifting to the quality of the food they consume and its contributions to improved health.

The situation in many developing countries—especially in Africa—is different. Low-income families in these countries are faced with a wide range of challenges that include malnutrition, hunger and related illnesses. Addressing these challenges requires deployment of the available technological options. The poor often rely on a limited range of food sources and as ecological degradation continues, the capacity to meet their needs diminishes. Raising agricultural productivity while promoting sustainable land use becomes a key development goal. Indeed, in many poor regions of the world agricultural production is done by women who also have other critical household responsibilities.

Responding to these challenges requires investment in technologies that are appropriate to the needs of low-income communities living in diverse ecological zones often located in areas that are not served by major markets. Agricultural production in these areas will need to be equally diverse and to reflect local needs and preferences. Genetic modification and the emerging techniques of genomics offer the possibility to design farming systems that are responsive to local needs and reflect sustainability requirements. In other words, genetic modification and genomics make it possible to design farming systems that are decentralized, responsive to local needs and more productive than existing methods.

2. DIVERGENT TECHNOLOGICAL TRAJECTORIES

The capacity to modify living organisms to perform new functions offers humanity the potential to make the transition from classical farming methods to decentralized production systems that are consistent with ecological principles. It is because of this adaptive potential that developing countries have been particularly interested in building capacity in this field. Let us take the African region as an example. The green revolution only partially touched this continent. Advances in maize breeding helped to extend the scope of food production in many countries. Efforts in other areas showed dismal results. There are many reasons for this. First, the cold war concerns that inspired the Green Revolution in Latin America and Asia took on a different character in Africa.[20] Raising food productivity was not a strategic way of responding to superpower competition in the region. As a result, promoting agricultural research was not given the kind of priority that it received in other regions.

The Green Revolution relied on a long history of prior research and accumulated knowledge on corn, wheat and rice and focused on limited technical tasks such as raising yields using increased inputs. Africa's food consumption patterns did not lend themselves to large-scale use of these crops. Africa lacked the institutional foundations for research in these crops. Subsequent efforts to create research institutions that focused on tropical crops have not registered the same levels of productivity gains and impacts as wheat, rice

20. Perkins, J. (1997). *Geopolitics of the Green Revolution: Wheat, Genes, and the Cold War*. Oxford, UK: Oxford University Press.

and corn. In fact, the fate of these institutions now hangs in the balance, as international assistance to tropical agriculture declines and most international agricultural institutions fail to keep up with the demands of a changing global knowledge system.

There are, however, other ecological factors that set Africa apart from other continents. Much of the continent is arid or semi arid and marked by ecological diversity.[21] These variations are associated with mosaics of productive activity with limited scope for the kind of mass agricultural production that has been promoted in other regions of the world. Agricultural research to meet the needs of isolated rural populations was beyond the reach of traditional plant breeding institutions. Moreover, the sheer diversity of crops used in the region and the absence of large markets undermines the feasibility of approaches adopted during the Green Revolution.

Today's technological capabilities in fields such as genomics make it possible to adapt crops to these diverse ecosystems in ways that are consistent with the principles of sustainable agriculture. Herbicide resistance, disease and stress tolerance and other traits can be applied to promote sustainable agriculture in regions that do not support agriculture today. It is this technological flexibility and the creation of niche markets that developing countries hoped to use to improve their farming methods and reduce pressure on the environment. But the evolution of biotechnology has taken a different path with a focus on markets of the industrialized world or the temperate regions. This is partly because of the logic of technological agglomeration that favors the accumulation of knowledge in areas with previous investments in technological capabilities and supportive institutions. Developing countries that need biotechnology most are also the ones least involved in its development.

Table: 1: Global coverage of transgenic crops by country, 2001 (Million Ha)

USA	35.7
Argentina	11.8
Canada	03.2
China	01.5
South Africa	00.2
Australia	00.2
Mexico	<0.1
Bulgaria	<0.1
Uruguay	<0.1
Romania	<0.1
Spain	<0.1
Indonesia	<0.1
Germany	<0.1

Source: James, C. (2002) *Global Review of Commercialized Transgenic Crops: 2001*. Ithaca, New York: International Service for the Acquisition of Agri-Biotech Applications.

21. Conway, G. (2003). *From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century*. Director's Forum. Washington, DC: Woodrow Wilson International Center for Scholars.

The use of transgenic crops has been expanding rapidly, but this diffusion has been in the temperate regions (Table 1). Most of this coverage is in large farms where genetic modification has been used to introduce incremental changes in existing crops.[22] These incremental adjustments in crops explain why the distribution of transgenic crops is limited to geographical areas with similar ecological conditions.

Transgenic applications are used mainly in crops such as soybean, corn, canola and cotton. The bulk of the crops contain traits for herbicide tolerance and disease resistance. These trends show that the early diffusion of transgenic crops has been largely in the temperate regions and has been limited to a few major commercial crops. The promise of biotechnology to meet the needs of low-income families in the developing world still remains a distant dream.

Table 2: Transgenic food crops being tested in developing countries: a sample

Beans	Potato
Cabbage	Rape
Cauliflower	Rice
Chili	Soybean
Maize	Squash
Melon	Strawberry
Mustard	Sugarcane
Papaya	Sweet potato
Peanut	Tomato
Pepper	Wheat

Source: Toenniessen, G., J.C., O'Toole, J. DeVries. (2003). Advances in Plant Biotechnology and its Adoption in Developing Countries. *Current Opinion in Plant Biology*, 6 (1-8).

There are two main reasons why the promise has not been realized. First, crop development for low-income families has traditionally been carried out by the public sector. But biotechnology has emerged from the private sector, which lacks the incentives to invest in crops for poor people.[23] Second, agricultural research in the public sector has been declining over the years. It is unlikely that the situation will change without a redirection of existing research priorities in private enterprises through the provision of appropriate incentives, as well as a significant increase in public sector funding for agricultural research.[24] In addition, institutional arrangements will need to be created to facilitate closer cooperation between private and public-sector institutions.

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22. Juma, C. (2000) "The UN's role in the new diplomacy", *Issues in Science and Technology*, XVII(1):37–38.
23. Pingali, P.L., G. Traxler. (2002). "Changing Locus of Agricultural Research: Will the Poor Benefit from Biotechnology and Privatization Trends?" *Food Policy*, 27: 223-238; Byerlee, D., K. Fisher. (2002),. "Accessing Modern Science: Policy and Institutional Options for Agricultural Biotechnology in Developing Countries," *World Development*, 30(6): 931-948.
24. Pray, C., D. Umali-Deininger. (1998). "The Private Sector in Agricultural Research Systems: Will it Fill the Gap?" *World Development*, 26(6):1127-1148.

The divergence in technological evolution is likely to be reinforced by three factors. First, the continuing uncertainty over market access for GM products in Europe will reduce the pace of technological innovations in products intended for international markets.[25] Indeed in the short-run, premium markets now exist for non-GM crops. This general trend could discourage investment in biotechnology research and as a consequence slow down technological development in developing countries. Secondly, developing countries that are engaged in biotechnology are likely to redirect their efforts towards meeting local needs. Many of the products of developing countries are destined for local consumption, partly because of urgency in this field and partly because of uncertainty in international markets.[26] Third, a number of biotechnology firms in the industrialized world are willing to share their technology on condition that it is used to address local food needs and not in export crops. Several enterprises have granted royalty-free uses of their inventions for the development of rice enhanced with vitamin A, on condition that the product is grown only by farmers earning less that $10,000 a year. Monsanto has licensed its technology to Kenya royalty-free for use in the development of virus-resistant sweet potatoes for local consumption.

3. REDIRECTING TECHNOLOGICAL EFFORT

Efforts to redirect biotechnology to address the needs of low-income families in developing countries should be placed in a large policy framework that addresses other social issues. More importantly, such strategies should be part of policies designed to use science and technology to achieve sustainable development goals.[27] In addition, biotechnology should be considered as one of the tools in a larger portfolio of technological options. In this regard, biotechnology is simply a set of tools and the embodied knowledge needed to solve specific problems. How this is done depends largely on the choice of problems and nature of institutional arrangements in which the technology is issued. Efforts that seek to curtain the diffusion of biotechnology therefore limit the ability of developing countries to design technological mixes that suit their specific circumstances.

This view does not imply that technology is neutral. The choice of technological trajectories often reflects the economic, social and cultural context in which it emerges. Use of technology does not always reproduce the same conditions that characterized its origins. Technologies are often modified and adapted to reflect new socio-economic conditions, depending on prevailing social goals. Indeed, it is the flexibility that is embodied in biotechnology techniques that makes it possible for them to be applied under different farming systems. It is true that biotechnology is currently used mainly in large-

25. Phillips, P., D. Buckingham. (2001). "Agricultural Biotechnology, the Environment, and International Trade Regulation", In Michelmann, H.J., J. Stabler, G. Storey. (eds.) *Globalization and Agricultural Trade Policy*. Boulder, Colorado, USA: Lynne Rienner Publishers, pp. 67-96; Sheldon, I.M. (2002). "Regulation of Biotechnology: Will We Ever 'Freely' Trade GMOs?" *European Review of Agricultural Economics*, 29(1): 155-176.
26. Toenniessen, G., J.C., O'Toole, J. DeVries (2003). Advances in Plant Biotechnology and its Adoption in Developing Countries. *Current Opinion in Plant Biology*, 6(1-8).
27. Juma, C. (2002). "The Global Sustainability Challenge: Fom Agreement to Action", *International Journal on. Global Environmental Issues*, 2(1/2): 1–14.

scale agriculture in the USA. But it is also true that the same technology is being used in small-scale agriculture in China, Mexico, India, South Africa and Kenya. What matters is therefore the choice of farming systems.

The choice of technology should be driven by the determination of local needs. Many developing countries have already indicated in their various agricultural development priorities that could be addressed using genetic modification. Many African countries, for example, lie in regions where drought-tolerance, disease resistance and crop yield increases are priorities. Crops such as cassava, millet, yams, millet and sorghum are prime candidates for genetic modification. Modifications that seek to prolong the shelf life of foods could have a significant impact on reducing post-harvest losses. The use of herbicide tolerance in low-till agriculture is another area of priority, especially in helping to lessen farm labor and providing farm workers—most of whom are women—with opportunities to engage in other activities.

Another potential area for biotechnology application is the development of livestock tolerant to tropical diseases and stresses. Modern methods such as genomics could be applied in this area without requiring genetic modification. Also related to agricultural production is the significance of re-vegetation in marginal areas. Investment in fast-growing plants could help facilitate ecological restoration in many denuded regions of the world. Such research could also help fulfill the fodder requirements of these countries.

Redirecting global research and development efforts to focus on these challenges will entail considerable international cooperation, increases in public sector funding and incentives for private enterprises. It will also take the creation of an atmosphere that is tolerant to the use of emerging technologies in implementing sustainable development goals. But where international cooperation is not possible, bilateral responses that might include realignments in international trade relations will become the only option open to countries that view biotechnology as strategic to their mutual interests. Such a scenario is already emerging under bilateral cooperation arrangements being signed between countries with strong biotechnology-based industries.

Many developing countries are reluctant to engage in biotechnology development because they fear some industrialized countries would erect barriers against their products. These concerns are real and have fostered an atmosphere of distrust that is likely to undermine not only the global trading system, but also the ability of developing countries to meet their human needs.

Mar-25-03 07:42pm From- 202-225-0697 T-952 P.002/002 F-616

J. Dennis Hastert
Fourteenth District
Illinois

(202) 225-0600

Office of the Speaker
United States House of Representatives
Washington, DC 20515

January 29, 2003

The Honorable George W. Bush
The President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President,

We are writing today in support of the U.S. Government taking a case against the European Union (EU) to the World Trade Organization (WTO) to protest their restrictions against the importation of genetically modified foods. The European Union's moratorium on agricultural biotechnology has been in place for over four years with no end in sight. This policy has translated into an annual loss of almost $300 million in exports for U.S. farmers. However, it should be noted that this is a policy based on prejudice and misinformation and not on sound science.

The U.S. government has safely regulated biotechnology since its inception in the 1970s. And with the rapid evolution of plant biotechnology in the early 1980s, additional regulation was added. As a result, the "Coordinated Framework for Regulation of Biotechnology" was adopted which apportions regulatory responsibility to the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). These agencies, working within the coordinated framework and existing laws, evaluate the safety of plant biotechnology products from inception to final approval.

Although traditionally bred plants generally do not need federal pre-market approval, plant biotechnology products are screened by at least one, and often by as many as three, federal agencies. From conception to commercial introduction, it can take up to 10 years to bring a biotech plant to market. Regulatory oversight is constant throughout the process; in fact, there are ten separate points at which federal regulators can question and/or halt development of a biotech plant variety. Throughout, the public has ample opportunity for participation and comment, and data on which regulatory decisions are based are readily available.

Nonetheless, the EU has been steadfast in their refusal to admit these products; despite the fact that their own scientists agree that genetically modified foods are safe. This is simply a non-tariff barrier based on politics and protectionism, not science.

While your Administration has continued to negotiate this issue with the EU, we have seen alarming consequences as a result of the moratorium. In the last few months, developing African nations have rejected much-needed U.S. food aid because the shipments contained corn produced with scientifically-proven biotechnology. This is of great concern since it appears these countries fear that EU countries would no longer accept their own food exports because genetically modified seeds may spread to domestic crops.

In addition, China has developed new rules for the approval and labeling of genetically modified farm products that have been temporarily delayed. In the interim, however, conflicting rules and management difficulties may impede U.S. soybean exports while China works out the details of its regulations. Since an overwhelming proportion of the U.S. soybean crop is genetically modified, GMO regulations could impact on the nearly $1 billion of U.S. soybean exports to China. The spread of non-scientifically based barriers to trade simply must be halted.

To that end, we respectfully urge the U.S. government to formally take a case to the WTO in the case of the EU's moratorium on agricultural biotechnology. This is clearly a non-tariff barrier with no scientific basis that can no longer be allowed to persist. Gone unchallenged, the global impact this discriminatory policy would be disastrous for U.S. farmers and their ability to provide an abundant reliable product for the world's population at a time when dozens of countries are currently experiencing serious food shortages.

While some have argued that pursuing official WTO action will not solve the problem of access, it is our view that official action would send a message to countries around the world that prohibitive policies on biotechnology are illegal, not based on sound science and detrimental to the pursuit of ending world hunger.

Furthermore, the failure of other countries to develop consistent and science-based regulatory processes governing biotechnology has the potential to constrain scientific innovation and disrupt trade more generally. Sound science must be the cornerstone of any product approval process.

Already, approximately 800 million people are malnourished in the developing world, and another 100 million go hungry each day. Agricultural biotechnology can be used to help these farmers produce better yields through drought-tolerant varieties, which are rich in nutrients and more resistant to insects and weeds. Halting or even slowing down the development of this technology could have dire consequences for countries where populations are growing rapidly and all arable land is already under cultivation.

We appreciate the work you have done on this issue. Throughout this country, rural America provides us with the safest and most inexpensive food supply in the world. Their goal is to share this gift with those who need it most, while at the same time having access to markets around the world.

We look forward to working with you on this very important issue.

Sincerely,

J. Dennis Hastert
Speaker

Roy Blunt
Majority Whip

Bob Goodlatte
Member of Congress

Richard Pombo
Member of Congress

Gil Gutknecht
Member of Congress

Robin Hayes
Member of Congress

Bill Jenkins
Member of Congress

Frank Lucas
Member of Congress

Jerry Moran
Member of Congress

Frank Wolf
Member of Congress

Statement of Dr. Florence Wambugu*
President, A Harvest Biotech Foundation International
Nairobi, Kenya

Submitted to the Committee on Agriculture
United States House of Representatives

Hearing on
"Review of Artificial Barriers to United States Agricultural Trade and Foreign Food Assistance"

March 26, 2003

Thank you, Mr. Chairman. I am grateful for the opportunity to submit testimony to the Agriculture Committee on critical issues in biotechnology, foreign food aid, and African agriculture.

I am a passionate believer in the power of biotechnology to boost food production and fight hunger and poverty in the developing world. As one of nine children growing up on a small farm in Kenya, I know that African farmers need more tools for fighting plant diseases and overcoming other barriers to increased crop production. I do not believe that biotechnology is a silver bullet for African agriculture, but it is an indispensable tool that can have dramatic benefits.

The African continent, more than any other, urgently needs agricultural biotechnology, including transgenic crops, to improve food production. This is why the debate over providing genetically modified (GM) corn in food aid shipments is so troubling. The primary accomplishment of the mainly European anti-biotech lobby, through gross misinformation and political maneuvering, was only to keep safe and nutritious food out of the hands of starving people.

However, these cynical organizations also used famine as an opportunity to promote an anti-biotech message that not only undermines the most promising developments in African agriculture, but also further distorts the global debate over biotechnology. African scientists, who overwhelmingly support the development of biotechnology for African agriculture, have a common interest with you in fighting for open minds and markets around the world.

It is a paradox that one of the most controversial sciences—biotechnology—has become a unifying factor for African scientists. Given the controversies surrounding the science, arriving at a consensus position has not been easy. But biotechnology has gained acceptance because there is consensus that it is a global opportunity. Both multinational companies and small-holder farmers stand to benefit as confirmed by experiences in China and Africa. While the focus has been on benefits to the private sector, programs such as the tissue culture banana project in some

* Dr. Florence Wambugu is the Founder and President of A Harvest Biotech Foundation International. A Harvest can be found on the web at www.ahbfi.org. Its offices are located in Nairobi, Kenya; Johannesburg, South Africa; and Washington, DC. Dr. Wambugu is the author of "Modifying Africa: How Biotechnology Can Benefit the Poor and Hungry - A Case Study from Kenya," which can be found on the web at www.modifyingafrica.com.

East African countries have demonstrated that biotechnology can have a positive impact on hunger, malnutrition and poverty. In some cases, rural farm incomes have tripled as a result of biotech techniques.

The question then arises: Should the agricultural sector remain unchanged while every other aspect of life on the continent is changing? The anti-biotech lobby asserts that the continent needs to be protected from big multinational biotech companies. This often Euro-centric view is founded on two premises: that Africa has no expertise to make an informed decision and that the continent should focus on organic farming. These perspectives, even if well intended, do not represent the African scientists' view.

Throughout my career I have been dedicated to realizing the promise of biotechnology for small farmers and communities in Africa and other areas of the world where producing sufficient food is a constant struggle. I bring global experience and a global perspective to my work. I obtained a bachelors degree in Biological Sciences from the University of Nairobi in Kenya, a masters degree in Plant Pathology from the University of North Dakota, a PhD in Plant Virology and Biotechnology at the University of Bath. I also spent a three-year post doctoral fellowship in genetic engineering with Monsanto here in the United States, during which time I worked on developing a genetically modified, virus resistant sweet potato.

Most recently I was Director of the African Region Office of the International Service for the Acquisition of Agri-biotech Applications, and earlier I was the Senior Research Officer and Coordinator of Plant Biotechnology Research with the Kenya Agricultural Research Institute. Among other international activities I serve on the Dupont Biotech Advisory Panel, the Board of Trustees of the International Plant Genetics Resource Institute, and the private sector committee of the Consultative Group on International Agricultural Research.

I founded and became President of A Harvest Biotech Foundation International in 2002 to improve the quality and impact of biotechnology communications and to help facilitate the development and adoption of biotech crops in Africa. A Harvest is focused on biotechnology education and facilitating the delivery of biotechnology benefits to farmers. I travel frequently around the world to speak about the crop production problems facing Africa and the solutions that biotechnology offers.

Did Zambia have any valid reasons for rejecting GM food? No. But Zambia did have valid reasons for asking questions about trade and food safety issues. First, brushing aside the issue of trade with the European Union (EU) is simplistic. But total rejection of GM food is equally simplistic. For historical, political and economic reasons, Africa's main trading partner is Europe. In view of the EU moratorium on GM food, African countries that favor the use of GM crops must put on their thinking caps and decide how best to deal with the trade issue. My country, Kenya, has discovered that in the last five years, neighboring Uganda has become our largest trading partner, overtaking Britain. Regionally, the Common Market for Eastern and Southern Africa has recently surpassed the EU as Kenya's main trading bloc. These are relevant lessons for Zambia.

The second issue is one of safety. As a scientist, who has been in the lab and have been involved in biotechnology for over 10 years, I can confirm that rigorous testing takes place to ensure GM foods are safe. Indeed, a number of the foods that we eat would fail miserably if passed through the rigor of GM food testing. There are no proven dangers from GM foods, although even pro-GM scientists would agree there are always *potential* dangers. Mobile phone technology is spreading like wild fire in Africa, despite the alleged danger of cancer-causing effects. Should we stop using cell phones? The simple answer is that the benefits far outweigh any potential dangers.

The needs of Africa and Europe are different. Europe has surplus food and does not experience hunger, mass starvation and death on the scale we frequently and sadly witness in Africa. The priority of Africa is to feed her people with safe foods and to sustain agricultural production and the environment. Based on what is happening on the continent, it is a foregone conclusion that biotechnology is causing a silent revolution in Africa. Farmers have embraced the new technology because it makes them more efficient, protecting—or increasing—yields and reducing their reliance on chemicals.

The debate on biotechnology and its impact on Africa has already moved to a higher level. The issue is not whether to adopt biotechnology, but how to adopt it. The challenge now surrounds substantive matters related to the technology and specific policies and institutions required to enable Africans maximize the benefits and minimize potential risks associated with biotechnology.

Most African countries lack the necessary expertise and information to engage in the formulation and implementation of long-term biotechnology policies and laws. At the moment they are merely reacting to political and ethical issues being raised by anti-biotechnology lobbies around the world. Africa needs a critical mass of African expertise in biotechnology policy analysis in order to enlarge the region's ability to participate effectively in the international negotiations, such as the Protocol on Biosafety.

However, it must also be emphasized that Africa has comparative advantages in biotechnology. We can participate in this global opportunity as equal partners. While the industrialized countries bring technology to the table, Africa is bringing its enormous genetic diversity, indigenous knowledge, local field ecosystems for product development, capacities and infrastructure required by foreign multinational companies. Africa has local germplasm, some of it already well-characterized and clean, being held in gene banks in trust by centers run by the Consultative Group of International Agricultural Research.

Our interest is in unpacking the emerging opportunities with a view to transforming rural agriculture without undermining local ecologies and socio-economic landscapes. Instead of knee-jerk reactions to biotechnology, African governments must now move aggressively to establish technology policies that enlarge their—and the continent's—comparative advantages and competitiveness in the technology.

Critics of biotechnology claim that Africa has no chance to benefit from biotechnology, and that Africa will only be exploited by multinationals. On the contrary, small-scale farmers in Africa

have benefited by using hybrid seeds from local and multinational companies, and transgenic seeds in effect are simply an added-value improvement to these hybrids. Local farmers are benefiting from tissue-culture technologies for banana, sugar cane, pyrethrum, cassava and other crops. There is every reason to believe they will also benefit from the crop-protection transgenic technologies in the pipeline for banana, such as sigatoka, the disease-resistant transgenic variety now ready for field trials. Virus- and pest-resistant transgenic sugar cane technologies are being developed in countries such as Mauritius, South Africa and Egypt.

Kenya – which is currently drafting laws to govern GM foods – has opted to build capacity in every area necessary to adopt biotechnology, while moving with care. We appreciate that there could be potential dangers, but we also know very well the benefits. For example, let's look at the effect of GM technology on three important crops in Africa.

Crop	**World (Ave Yield: tones/ha)**	**Africa (Ave Yield: tones/ha)**
Maize	1.7	4.1
Sweet potatoes	4.8	14.7
Bananas	6.0	48.1

As is clearly evident, with GM technology Africa can quadruple its maize output, more than triple sweet potato output and increase banana output by eight times. Anybody who cares about hunger should be interested in this technology. It is my considered opinion that biotechnology is already having a major impact on agricultural and public policies in Africa from a continental level.

The Forum for Agricultural Research in Africa (FARA) recently adopted biotechnology as one of its three main goals. FARA is important in the current GM debate because it brings together Africa's key decision makers in agriculture. It is also through FARA that the New Partnership for African Development (Nepad) will shape a continental agricultural strategy. Both FARA and Nepad share the common goal of achieving a continent-wide 6% per annum growth in agricultural sector over the next 20 to 25 years. There is no doubt at the continental level that biotechnology will play a critical role in shaping the future of Africa.

In my view, African policy-makers and scientists need to urgently identify specific areas of biotechnology in which their countries should invest. Debate must shift to the nature of innovative policies and laws to regulate the application of genetic engineering to ensure that potential risks are reduced or altogether eliminated. Other important areas of focus include mapping global trends in biotechnology, the socio-economic benefits of biotechnology to African countries, and the role of intellectual property protection in promoting the transfer of safe biotechnology techniques and products to Africa.

Needless to say, Africa has many problems—a shortage of skilled people (especially in biotechnology), poor research funding, lack of governing policies, and civil strife. Nevertheless, countries such as South Africa, Egypt, Zimbabwe and Kenya are taking practical steps to ensure that they can use biotechnology for sustainable development.

African countries need the right policies and agencies, such as operational biosafety regulatory agencies and an effective local public and private sector, to interface with multinational companies that already have the technologies. Consumers need to be informed of the pros and cons of various agricultural biotechnology packages, the dangers of using unsuitable foreign germplasm, and how to avoid the loss of local germplasm and to maintain local diversity.

Other checks and balances are required to avoid patenting local germplasm and innovations by multinationals; to ensure policies on intellectual property rights and to avoid unfair competition; to prevent the monopoly buying of local seed companies; and to prevent the exploitation of local consumers and companies by foreign multinationals. Field trials need to be done locally, in Africa, to establish environmental safety under tropical conditions.

The main goal is to find a balanced formula for how local institutions can participate in transgenic product development and share the benefits, risks and profits of the technology, as they own the local germplasm needed by the multinationals for sustainable commercialization. New varieties must not simply replace local ones. The removal of genes that were in the public domain into the private sector raises concern in Africa.

All these issues mean that Africa must strengthen its capacity to deal with various aspects of biotechnology, including issues of biosafety, creating and sustaining gene banks, and encouraging the emergence of a local biotechnology private sector.

We may have missed the green revolution, which helped Asia and Latin America achieve self-sufficiency in food production, but we cannot afford to be excluded or to miss another major global technological revolution. The people of Africa cannot wait for others to debate the merits of biotechnology—and we look to America and other developed nations to help us allocate technologies that can prevent suffering and starvation.

National Corn Growers Association
www.ncga.com

U.S. GRAINS COUNCIL

January 29, 2003

The Honorable George W. Bush
President of the United States
The White House
Washington, DC 20500

Dear President Bush:

Over the past five years, United States corn growers have lost sales approaching one billion dollars due to a de facto moratorium on the approval of agricultural products enhanced through modern biotechnology. As the European Union (EU) Commission readily admits, this moratorium has no scientific basis. In fact, scientific research proves corn derived from biotechnology is safe for human consumption and poses no adverse risk to the environment. Despite countless scientific studies, the continuing moratorium is leading to a larger humanitarian crisis in Sub-Saharan Africa.

The United States Agency for International Development estimates that up to 35 million people in Africa will need food aid through the end of this year, including 6.7 million people (49 percent of the population) in Zimbabwe and 2.9 million in Zambia. These numbers are growing daily in the region. While the United States has sent food aid to these countries, special interests in the region are encouraging African governments to reject the shipments because they contain corn derived from biotechnology.

The National Corn Growers Association and the U.S. Grains Council applaud statements from Ambassador Zoellick and Members of Congress condemning the EU moratorium. Our members believe it is highly irresponsible to play politics with starving populations.

The United States has exercised considerable patience as the EU grapples with the internally sensitive political issue of biotechnology acceptance. However, our members believe it is now time to engage the EU in a World Trade Organization (WTO) dispute settlement proceeding challenging its de facto moratorium. The hysteria propagated by anti-biotechnology officials and non-governmental organizations in Europe must stop. This is not only an agricultural issue, but also one that fundamentally challenges the humanitarian ideals of developed nations to help starving people around the globe.

We urge you to begin dispute settlement action in the WTO as soon as practicable. We stand ready to assist you in any way and thank you for your attention to this important issue.

Sincerely yours,

Fred Yoder
President
National Corn Growers Association

Don Jacoby
Chairman of the Board
U. S. Grains Council

[COMMITTEE PRINT 106-B]

SEEDS OF OPPORTUNITY: AN ASSESSMENT OF THE BENEFITS, SAFETY, AND OVERSIGHT OF PLANT GENOMICS AND AGRICULTURAL BIOTECHNOLOGY

REPORT PREPARED BY

CHAIRMAN NICK SMITH

OF THE

SUBCOMMITTEE ON BASIC RESEARCH

AND TRANSMITTED TO THE

COMMITTEE ON SCIENCE

FOR THE

ONE HUNDRED SIXTH CONGRESS
SECOND SESSION

April 13, 2000

Printed for the use of the Committee on Science

LETTER OF TRANSMITTAL

April 13, 2000

The Honorable James F. Sensenbrenner, Jr.
Chairman
Committee on Science
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

I am submitting herewith a Chairman's Report providing an assessment of the benefits, safety, and oversight of plant genomics and agricultural biotechnology. It is a summation of the findings of a series of three hearings held during the First Session of the 106th Congress by the Subcommittee on Basic Research entitled, "Plant Genome Science: From the Lab to the Field to the Market."

Agricultural biotechnology has come of age. It is referred to under different names—genetic engineering, gene splicing, bioengineering, recombinant DNA technology. But no matter the name used to describe it, this technology represents the latest tool in the continuum of techniques that plant breeders have developed and adopted over centuries. What is truly powerful about this technology is that it allows individual, well-characterized genes to be transferred from one organism to another, thus increasing the genetic diversity available to improve important commercial crop plants. The potential benefits to mankind are limited only by the resourcefulness of our scientists.

Biotechnology has been used safely for many years to develop new and useful products used in a variety of industries. More than a thousand products have now been approved for marketing, and many more are being developed. These products include dozens of therapeutics, including human insulin for diabetics, growth factors used in bone marrow transplants, products for treating heart attacks, hundreds of diagnostic tests for AIDS, hepatitis, and other infectious agents, enzymes used in food production, such as those used for cheese, and many others.

And this is just the beginning. In agriculture, new plant varieties created with these techniques will offer foods with better taste, more nutrition, and longer shelf life, and farmers will be able to grow these improved varieties more efficiently, leading to lower costs for consumers and greater environmental protection. Soybeans that produce high oleic oil containing less saturated fat and requiring less processing, cotton plants that fight pests or produce naturally-colored cotton reducing the need for chemical dyes, and bananas that deliver vaccines to fight enteric diseases are just a few examples of what is in store.

While millions of lives all over the world have been protected and enriched by biotechnology, its application to agriculture has been coming under attack by well-financed activist groups. The controversy they have generated revolves around three basic questions: (1) are agricultural biotechnology and classical breeding methods conceptually the same; (2) are these products safe to eat; and (3) are they safe for the environment?

The testimony and other material made available to the Subcommittee lead me to conclude that the answer to all three questions is a resounding, "Yes." In fact, modern biotechnology is so precise, and so much more is known about the changes being made, that plants produced using this technology may be even safer than traditionally-bred plants.

This Report contains background information on the development and oversight of plant genetics and agricultural biotechnology, a summary of Subcommittee hearings and my findings and recommendations based on these hearings. I hope that it will be of use to you and to other Members of Congress, the Administration, States, and the general public interested in gaining a greater appreciation of the incredible potential of plant genomics and agricultural biotechnology.

Sincerely,

NICK SMITH
Chairman
Subcommittee on Basic Research

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SUMMARY

The Subcommittee on Basic Research of the Committee on Science held a series of three hearings entitled, "Plant Genome Research: From the Lab to the Field to the Market: Parts I-III," to examine plant genomics, its application to commercially-important crop plants, and the benefits, safety, and oversight of plant varieties produced using biotechnology. The testimony and other information presented at these hearings and information gathered at various briefings provides the basis for the findings and recommendations in this report.

Almost without exception, the crop plants in use today have been genetically modified. The development of new plant varieties through selective breeding has been improving agriculture and food production for thousands of years. In the 19th century, the basic principles of heredity were discovered by Gregor Mendel, whose studies on inheritance in garden peas laid the foundation for the modern science of genetics. Subsequent investigations advanced our understanding of the location, composition, and function of genes, and a critical breakthrough revolutionized the field in 1953, when James Watson and Francis Crick described the double helix structure of deoxyribonucleic acid (DNA), the substance of heredity. This groundbreaking research set the stage for deciphering the genetic code and led to the rapid advances in practical application of genetics in medicine, animal science, and agriculture.

The development of the science of genetics in the 20th century was a tremendously important factor in the plant breeding programs that have produced the remarkable diversity of fruits, vegetables, and grains that we enjoy today and that provide food security for the poor nations of the world. Traditional cross-breeding has been very useful in improving crop plants, but it is a time consuming process that results in the uncontrolled recombination of tens of thousands of genes, commonly producing unwanted traits that must be eliminated through successive rounds of backcrossing. Improving crops through traditional methods also is subject to severe limitations because of the constraints imposed by sexual compatibility, which limit the diversity of useful genetic material.

With the arrival of biotechnology, plant breeders are now able to develop novel varieties of plants with a level of precision and range unheard of just two decades ago. Using this technology, breeders can introduce selected, useful genes into a plant to express a specific, desirable trait in a significantly more controlled process than afforded by traditional breeding methods.

U.S. farmers have been quick to adopt plants modified using new biotechnology, including commercial crops that resist biologically insect and viral pests and tolerate broad-spectrum herbicides used to control weeds. As our knowledge of plant genetics expands, new varieties of plants with improved nutrition, taste, or other characteristics desired by consumers will become available. The federally-funded plant genome program provides much of the essential basic research on plant genetics required to develop new varieties of commercially important crops through advanced breeding programs.

For over two decades, the application of biotechnology has been assessed for safety. Oversight of agricultural biotechnology includes both regulatory and nonregulatory mechanisms that have

been developed over the last five decades for all crop plants and conventional agricultural systems. Federal regulation of agricultural biotechnology is guided by the 1986 Coordinated Framework for Regulation of Biotechnology, which laid out the responsibilities for the different regulatory agencies, and the 1992 Statement on Scope, which established the principle that regulation should focus on the characteristics of the organism, not the method used to produce it. Three federal agencies are responsible for regulating agricultural biotechnology under existing statutes: the U.S. Department of Agriculture (USDA), which is responsible for ensuring that new varieties are safe to grow; the Environmental Protection Agency (EPA), which is responsible for ensuring that new pest-resistant varieties are safe to grow and consume; and the Food and Drug Administration (FDA), which is responsible for ensuring that new varieties are safe to consume.

Although biotechnology has had an uninterrupted record of safe use, political activists in Europe have waged well-funded campaigns to persuade the public that the products of high-tech agriculture may be harmful to human health and the environment. As a result of these efforts, public confidence in the safety of agricultural biotechnology has been seriously undermined in Europe. Many European countries have established new rules and procedures specifically designed to address "genetically-modified organisms," and these have had a detrimental impact on international trade in agricultural products.

The controversy over agricultural biotechnology now has spread to the United States, the world's largest grower of plants and consumer of foods produced using this technology. At the core of the debate is food safety, particularly the possibility that unexpected genetic effects could introduce allergens or toxins into the food supply. The use of antibiotic resistance markers also has been criticized as dangerous to human health. As a result, there have been calls for both increased testing and labeling requirements for foods created using biotechnology.

Environmental concerns also have been raised. It has been suggested, for example, that widespread use of plants engineered with built-in protection against insect and viral pests could accelerate the development of pesticide-resistant insects or could have a negative impact on populations of beneficial insects, such as the Monarch butterfly. It also has been argued that the use of herbicide-tolerant plants could increase herbicide use and that "superweeds" could be developed through cross-pollination between these plants and nearby weedy relatives.

Extensive scientific evaluation worldwide has produced no evidence to support these claims. Far from causing environmental and health problems, agricultural biotechnology has tremendous potential to reduce the environmental impact of farming, provide better nutrition, and help feed a rapidly growing world population. Crops designed to resist pests and to tolerate herbicides and environmental stresses, such as freezing temperatures, drought, and high salinity, will make agriculture more efficient and sustainable by reducing synthetic chemical inputs and promoting no-tillage agricultural practices. Stress-tolerant crops also will reduce pressure on irreplaceable natural resources like rainforests by opening up presently nonarable lands to agriculture. Other plants are being developed that will produce renewable industrial products, such as lubricating oils and biodegradable plastics, and perform bioremediation of contaminated soils.

Biotechnology will be a key element in the fight against malnutrition worldwide. Deficiencies of vitamin A and iron, for example, are very serious health issues in many regions of the developing

world, causing childhood blindness and maternal anemia in millions of people who rely on rice as a dietary staple. Biotechnology has been used to produce a new strain of rice—Golden Rice—that contains both vitamin A (by providing its precursor, beta-carotene) and iron. The Subcommittee heard about other research aimed at improving the nutrition of a wide variety of food staples, such as cassava, corn, rice, and other cereal grains, that can be a significant help in the fight for food security in many developing countries.

The merging of medical and agricultural biotechnology has opened up new ways to develop plant varieties with characteristics to enhance health. Advanced understanding of how natural plant substances, known as phytochemicals, confer protection against cancer and other diseases is being used to enhance the level of these substances in the food supply. Work is underway that will deliver medicines and edible vaccines through common foods that could be used to immunize individuals against a wide variety of enteric and other infectious diseases. These developments will have far-reaching implications for improving human health worldwide, potentially saving millions of lives in the poorest areas of the world by providing a simpler medicine production and distribution system.

Set against these benefits, however, is the idea that transferring a gene from one organism to an unrelated organism using recombinant DNA techniques inherently entails greater risks than traditional cross breeding. The weight of the scientific evidence leads to the conclusion that there is nothing to substantiate scientifically the view that the products of agricultural biotechnology are inherently different or more risky than similar products of conventional breeding.

The overwhelming view of the scientific community—including the National Academy of Sciences, the National Research Council, many professional scientific societies, the Organization for Economic Cooperation and Development, the World Health Organization, and the research scientists who appeared before the Subcommittee—is that risk assessment should focus on the characteristics of the plant and the environment into which it is to be introduced, not on the method of genetic manipulation and the source of the genetic material transferred. These risk factors apply equally to traditionally-bred plants.

Years of research and experience demonstrate that plant varieties produced using biotechnology, and the foods derived from them, are just as safe as similar varieties produced using classical plant breeding, and they may even be safer. Because more is known about the changes being made and because common crop varieties with which we have a broad range of experience are being modified, plants breeders can answer questions about safety that cannot be answered for the products of classical breeding techniques.

FDA has adopted a risk-based regulatory approach consistent with these principles and with the long history of safe use of genetically-modified plants and the foods derived from them. Its policies on voluntary consultation and labeling are consistent with the scientific consensus and provide essential public health protection.

Unlike FDA regulations on food, USDA has instituted plant pest regulations, and EPA proposes to institute new plant pesticide regulations, that target selectively plants produced using

biotechnology and apply substantive regulatory requirements to early stages of plant research and development. These regulations add greatly to the cost of developing new biotech plant varieties, harming both an emerging industry and the largely publicly-funded research base upon which it depends. Regulations and regulatory proposals that selectively capture the products of biotechnology should be modified to reflect the scientific consensus that the source of the gene and the methods used to transfer it are poor indicators of risk.

In the international arena, the United States should work to ensure that access to existing markets for agricultural products are maintained. The United States should not accept any international agreements that endorse the precautionary principle—which asserts that governments may make political decisions to restrict a product even in the absence of scientific evidence that a risk exists—and that depart from the principle of substantial equivalence adopted by a number of international bodies.

Finally, the Administration, industry, and scientific community have a responsibility to educate the public and improve the availability of information on the long record of safe use of agricultural biotechnology products. This is critically important to building consumer confidence and ensuring that sound science is used to make regulatory decisions.

INTRODUCTION

Throughout history, new scientific discoveries have challenged conventional thinking. Observations made by Galileo Galilei confirming the Copernican theory that the Earth revolves around the Sun challenged the authority of the Church in 17th century Italy and ushered in a new era of science. Marcello Malphigi was another 17th century scientist whose work was denounced by the established order, but it provided a foundation for advances in comparative anatomy. The history of science has many other examples of new discoveries that have been initially greeted with little enthusiasm. However, over the years society has learned to accept—indeed, celebrate—these discoveries and the social and intellectual benefits they have conveyed.

The introduction of new biotechnology methods in agriculture also has met with resistance. Traditionally, genetic enhancements of crop plants have come from breeding programs that capitalize on the natural variation between sexually compatible plants. In this process, plants exhibiting desirable traits—such as enhanced hardiness or resistance to pests, better yields, or fruits with improved flavor or shelf life—are identified and then introduced into plant breeding programs.

Selective breeding has been used for centuries to produce new plant varieties. However, hybridization, the most commonly-used technique, is subject to severe shortcomings. The plants must be sexually-compatible, which limits the diversity of the genetic material available for crossing, and the process results in uncontrolled combinations of thousands of uncharacterized genes.

Biotechnology has made it possible to produce precise genetic changes at the level of single, well-characterized genes selected from one organism and introduced into another. The plant's own genome also may be modified selectively to control, increase, or turn off specific functions within the plant.

Applications of biotechnology already have had a profound impact on fields such as biomedical research, medicine, and food processing, and over a thousand biotechnology products have been approved and are in use. In agriculture, biotechnology has been used to develop desirable characteristics in plants with more precision and knowledge than afforded by conventional breeding techniques. Some of these plants have been genetically modified to tolerate specific broad-spectrum herbicides. Others have been altered so that they are biologically protected against insect or viral pests, eliminating the need for some applications of synthetic pesticides.

Future varieties of plants could be enhanced to produce plants and foods with improved nutritional content or added health benefits, greater tolerance to environmental stresses such as drought, frost, or high salinity, and the ability to provide renewable sources of fuel, industrial oils, and plastics. The federally-funded plant genome program will provide much of the basic research that will be used to develop these new, improved plant varieties.

Despite an unblemished record of safe use, critics have mounted well-funded campaigns against this technology and have raised concerns about its potential impact on human health and the environment. In Europe, these campaigns and other unrelated foods scares have seriously

undermined public confidence in the safety of foods produced using this new, genetics-based science. In response, many European countries and the European Union have established new rules and procedures designed specifically to address "genetically-modified organisms." These actions have created an international trade conflict that has cost farmers hundreds of millions of dollars[1] and now threatens to drive scientists and agricultural researchers away from a field of research that has tremendous potential for solving food security and environmental problems.

Unlike in Europe, similar campaigns in the United States have not resulted in widespread antibiotechnology sentiment among the public. The reaction of U.S. industry, however, has been less sanguine. The first indication that these campaigns were having an effect was the decision announced by Gerber—a subsidiary of the Swiss pharmaceutical and biotechnology company Novartis—that it would no longer use biotech varieties of corn or soybean in its baby foods, even those grown from seeds developed by its parent company. Though little noticed, the company's announcement did not rule out using new bioengineered varieties providing enhanced nutrition and other benefits. Nevertheless, the decision by Gerber created the perception among the public that biotechnology foods were inherently different and less safe, without acknowledging that almost all foods the company sells have been genetically modified using traditional techniques. Many other companies have since followed Gerber's lead and discontinued the use of bioengineered foods in their products.

The ostensible basis for the attacks on biotechnology is the idea that transferring genes between unrelated organisms is unnatural and inherently entails greater risks than traditional cross breeding. At the core of this debate is food safety, particularly the possibility that unexpected genetic effects could introduce allergens or toxins into the food supply. The use of antibiotic resistance markers has been criticized as possibly dangerous to human health. These concerns have led to calls both for increased regulation and for mandatory labeling of biotech food products.

Concerns also have been raised about the impact of pest-resistant and herbicide-tolerant crops on the environment. For example, some biotechnology foes claim that widespread use of bioengineered pest-resistant plants could accelerate the development of pesticide-resistant insects or could have an negative impact on the populations of beneficial, non-target insects, such as the Monarch butterfly. It also has been suggested that the use of herbicide-tolerant plants actually will increase herbicide use and that "superweeds" could be developed through cross-pollination with nearby weedy relatives.

It is understandable that these negative claims could create a climate of unease about this new technology. Therefore, the Subcommittee on Basic Research conducted a series of public hearings during the First Session of the 106th Congress in which leading scientists were given the opportunity to assess these controversies. This Report is based on the testimony and other documents made available to the Subcommittee over the course of those hearings. It provides a brief history of agricultural biotechnology and its oversight, a discussion of findings concerning the benefits, safety, and environmental impact of agricultural plants modified using biotechnology, and a list of recommendations.

[1] According to the U.S. Department of Agriculture's Foreign Agriculture Service, the prolonged approval of U.S. varieties of biotech corn led to a $200 million loss for U.S. farmers in 1998 alone (Kelch, *et al.*, 1998).

SUBCOMMITTEE HEARINGS

The Subcommittee on Basic Research of the Committee on Science held a series of three hearings entitled, "Plant Genome Research: From the Lab to the Field to the Market: Parts I-III," to examine plant genomics, its application to commercially-important crops plants, and the benefits, safety, and oversight of plant varieties produced using biotechnology.

On August 3, 1999, the Subcommittee held the first of its hearings and heard testimony concerning current plant genome research projects and their application to industry, as well as the regulatory and market barriers to agricultural biotechnology products. Testifying before Subcommittee were: Dr. Mary Clutter, Assistant Director, Directorate for Biological Sciences, National Science Foundation (NSF); Dr. Eileen Kennedy, Deputy Assistant Secretary, Research, Education, and Economics, U.S. Department of Agriculture (USDA); Dr. Kenneth Keegstra, Director and Professor, Michigan State University Plant Research Laboratory, Michigan State University; Dr. John Ryals, Chief Executive Officer, Paradigm Genetics; and Dr. Susanne Huttner, Director of the Biotechnology Research and Education Program, University of California.

On October 5, 1999, the Subcommittee examined the benefits and risks involved in applying biotechnology to agricultural plants. Witnesses for this hearing included: Dr. Michael Thomashow, Professor of Plant and Soil Science, Michigan State University; Dr. Rebecca Goldburg, Director, Biotechnology Programs, Environmental Defense Fund (EDF); Dr. Abigail A. Salyers, Professor of Microbiology, University of Illinois; Dr. Anthony M. Shelton, Professor of Entomology, Cornell University; Dr. R. James Cook, Professor of Plant Pathology, Washington State University.

In addition, the Subcommittee received written testimony for the record from: Dr. Charles J. Arntzen, President and CEO, Boyce Thompson Institute for Plant Research and Adjunct Professor, College of Agriculture and Life Sciences, Cornell University; Dr. Roger N. Beachy, President, Donald Danforth Plant Science Center; Mr. Leonard P. Gianessi, Senior Research Associate, and Ms. Janet E. Carpenter, Research Associate, National Center for Food and Agriculture Policy; Dr. Brian A. Larkins, Porterfield Professor of Plant Sciences, Department of Plant Sciences, University of Arizona; and Dr. Channapatna S. Prakash, Professor and Director, Center for Plant Biotechnology Research, Tuskegee University.

On October 19, 1999, the Subcommittee held the final hearing in this series to review and assess current and proposed regulations for agricultural biotechnology. Witnesses at this hearing included: Dr. Sally L. McCammon, Science Advisor, Animal and Plant Health Inspection Service (APHIS), USDA; Dr. Janet Anderson, Director, Bio-Pesticide and Pollution Prevention Division, Environmental Protection Agency (EPA); Dr. James Maryanski, Biotechnology Coordinator, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA); Mr. Mark Silbergeld, Co-Director, Washington Office of Consumers Union; and Dr. Stephen Taylor, Professor of Food Technology, University of Nebraska. The Subcommittee also received written testimony for the record from Dr. Stephen C. Joseph, President and CEO, National Center for Genome Resources.

The record of these hearings is available in Committee on Science print Serial No. 106-60. All references to witness testimony include written testimony, oral testimony, and responses to follow-up questions submitted by the Subcommittee. Where practicable, other material referred to in this document has been included in the record of the hearings. An electronic version of the Report is available on the Committee on Science World Wide Web site at "http://www.house.gov/science." Site visits to universities conducting plant genomic and breeding research and meetings held with interested parties also were important in gathering information for this Report.

BACKGROUND

A Brief History of Plant Genetics and Agricultural Biotechnology

Almost without exception, the fruit, vegetable, and other crop plants grown commercially today have been genetically modified.[2] The adoption of new plant varieties developed through selective breeding has been improving the food supply for thousands of years. Since prehistoric times, farmers have selected seeds from the strongest, most desirable plants, and used them to produce the next generation of crops. This process of selection, combined with genetic modification through crossbreeding, has resulted in a wide range of crop plants suited for different purposes and adapted to particular regions.

The impact of plant selection and cross breeding on crop species has been tremendous. Although the wild ancestors of few plants, such as carrots, lettuce, and sunflowers, are readily identifiable, most important food crops have been altered to such an extent that their wild ancestors are unrecognizable, and in some cases they are unknown altogether. The closest wild relative of maize (*Zea mays*), for example, is teosinte (*Euchlaena mexicana*), which may alternatively be an ancestor, descendant, or sibling. Finding the precise connection between domesticated maize and its tropical-American ancestor has proved elusive despite extensive study.

Not all genetic modification, of course, relies on human intervention. By the 18th century, naturalists were able to identify many kinds of hybrid plants that clearly were the result of the natural combination of two varieties of plants. However, these observations, while useful, were not systematized in any way. For most of man's history, plant breeding understandably focused exclusively on results, with little regard for the hereditary mechanisms involved. That began to change in the 19th century.

The Science of Genetics Comes of Age

The basic principles of heredity were discovered by Gregor Johann Mendel, an Augustinian monk at Brunn, Austria (now Brno, Czech Republic). His now-classic studies on inheritance of traits in garden peas (*Pisum sativum*), begun in 1856 in a small monastery garden, laid the foundation for the modern science of genetics. Unlike previous investigators, who attempted to explain all variations, whether heritable or not, Mendel concentrated his efforts on a few traits observed in a controlled breeding program.

Mendel found that certain traits of the parent plants—such as tallness or dwarfishness, blossom color, seed shape and color, *etc.*—were distributed among offspring in ratios that never varied significantly, and thus were predictable. From these results, he posited a set of rules to explain how characteristics are passed from one generation to the next and theorized that the variability among the parent plants and their descendants was due to paired units of heredity.[3] The causal

[2] Though not really "crop" plants, wild berries provide examples of plant-derived foods that are widely consumed but have not been genetically modified through human intervention.

[3] Mendel owed much of his success to his selection of a plant species, the garden pea, that normally is self-pollinating—allowing him to use genetically pure varieties in his experiments—and is easily cross-pollinated. Subsequent studies by Mendel using hawkweed (*Hieracium*)—an apomitic plant able to produce seeds without

"factors" of heredity suggested by Mendel eventually were given the name "genes" by Wilhelm Johannsen in 1905.

Mendel's discoveries were first reported in an obscure Austrian journal in 1866, where they attracted little attention until 1900, when Hugo deVries in The Netherlands, Carl Erich Correns in Germany, and Erich Tschermak von Seysenegg in Austria independently rediscovered them while conducting their own studies on inheritance. In 1903, Walter Sutton concluded that hereditary information was located on chromosomes, and in 1911 it was postulated that genes were arranged linearly.

By the mid 1930s, it was widely speculated that deoxyribonucleic acid—DNA—was the critical constituent of genes. The existence of nucleic acid was discovered earlier, in 1869, by the Swiss biochemist Frederick Miescher, but little attention was paid to this finding until after the turn of the century, when research on nucleic acids increased. By the late 1920s, the basic chemistry of DNA had been determined. Although DNA was found to be concentrated largely in the chromosomes, many scientists nonetheless believed that the complex nucleoproteins associated with DNA were more likely to be the primary constituent of genes. By 1952, several investigations with bacteria and viruses, which have little or no nucleoproteins in their DNA, confirmed that DNA was responsible for transmitting genetic information.

Another crucial piece to the genetic puzzle fell into place during the 1940s, when two American biologists, George Beadle and Edward Tatum, investigated the transmission of hereditary traits in the fungus *Neurospora.* They showed that particular genes were responsible for particular enzymes and that genes regulated all biochemical functions. Since their pioneering work—for which they (along with Joshua Lederberg) received the 1958 Nobel Prize in physiology or medicine—the concept that each gene governs the formation of a single enzyme was refined. It is now recognized that genes control the formation of polypeptide strands,[4] or proteins, which comprise the "workhorses" of cellular metabolism in all living organisms.

A critical breakthrough occurred in 1953, when James Watson, an American biochemist, and Francis Crick, a British biophysicist, described the double helix structure of DNA. Using stereochemical techniques and evidence developed by Rosalind Franklin and Maurice Wilkins, whose x-ray diffraction studies of DNA suggested a double-spiral structure, Watson and Crick were able to construct a three-dimensional molecular model of DNA. For their work, Watson, Crick, and Wilkins shared the 1962 Nobel Prize in physiology or medicine.[5] This groundbreaking research set the stage for further studies aimed at deciphering the genetic code and led to rapid advances in the practical applications of genetics.

We now know that DNA is, as Watson and Crick demonstrated, a double helical structure made up of two long strands composed of only four simple base chemicals: adenine, thymine, guanine, and cytosine. The order in which these bases are linked forms the basis of the DNA code and

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fertilization—yielded results at odds with his previous results using peas. He died in 1884 little knowing the true significance of his work.

[4] A polypeptide strand is comprised of a string of amino acid polymers.

[5] Rosalind Franklin died of cancer at age 37, five years before the Nobel Prize was awarded to her colleagues Watson, Crick, and Wilkins. Nobel Prize rules do not allow the prize to be awarded posthumously.

provides the chemical mechanism for storing genetic information. Genes are segments of DNA that contain enough information to produce a polypeptide strand or protein that, in turn, determines the traits expressed in the organism. DNA governs every biochemical process within the cell and the organism and commonly is referred to as the "Blueprint of Life."

The field of molecular biology gained one of its most powerful tools—recombinant DNA (rDNA[6]) technology—in the early 1970s. In 1972, researchers at Stanford University created the first recombinant molecule. The scientists, led by Paul Berg, who received a Nobel Prize for the work, used enzymes found in bacteria—called "restriction enzymes"—to cut DNA from two different sources (a bacterium and a virus) and used a different enzymatic reaction to splice these two foreign pieces of DNA together into a functional, hybrid DNA molecule. In 1973, Stanley Cohen, another Stanford researcher, and Herbert Boyer of the University of California at San Francisco took this work one step further by transferring a recombinant molecule into a bacterium where it functioned alongside the bacterium's own genes. In doing so, they created the first rDNA, or "genetically engineered," organism.

While none of these researchers set out to create the technology we now call gene splicing, they and others were quick to recognize the potential usefulness of this new tool. In fact, shortly after these discoveries, one of the scientists (Boyer) became a co-founder of the world's first biotechnology company, Genentech, which used genetically-engineered bacteria to produce useful human therapeutics and diagnostics, thereby launching an entirely new industry.

Genetics and Classical Plant Breeding

The development of the science of genetics in the 20th century was tremendously important in improving plant breeding. Since the 1920s, refinements of traditional breeding techniques have produced new varieties of old crops with higher yields, greater resistance to pests and diseases, and other desirable qualities. Genetic modification through these methods has given a immense boost to agricultural productivity.

Before the principles of genetics were determined, plant breeders depended on practical knowledge and experience to develop improved crops. One of the most successful plant breeders in America, Luther Burbank, produced new varieties of potatoes and other vegetables and fruits using hybridization and selection without any formal botanical training or understanding of genetics. His first and most famous variety, the Burbank potato—still popular even today—was introduced in 1876 and planted extensively.

In 1908, the American botanist George Shull found that inbreeding tended to purify strains of corn while weakening the plant. By cross-breeding inbred strains, he developed hybrids of maize that produced higher yields than the original varieties from which the crosses were made, and suggested that these hybrids could be used on farms in place of the varieties normally used. However, the drawback with the single-cross method Shull developed was that subsequent generations of the plant lost vigor. This problem was addressed in 1918 with the development of

[6] There are other techniques used in biotechnology, such as recombinant RNA and cell fusion. For the purposes of this report, the acronym rDNA shall refer to all recombinant technologies.

the double-cross by Donald Jones of the Connecticut Agricultural Experiment Station.[7] For many years, most of the corn grown in the United States was from double-cross hybrid seed. Today, seed producers are able to use single-cross hybrids because modern inbred corn lines are much more robust than those developed in the early 20th century.

Techniques informed by a better understanding of the genetic basis of heredity have been used extensively in crop improvement worldwide. For many years, the development of hybrids for use in developing countries, particularly those in the tropics, lagged behind developments in industrialized countries. After World War II, the developing world began applying hybrids with great effect. The introduction of a dwarfing gene into wheat by Orville Vogel in the 1940s, led to a tremendous improvement in grain yields and began this trend. Subsequent work in the 1950s and 1960s led to further increases in yields of wheat, rice, and other important staple crops grown by subsistence farmers in the developing world. Norman Borlaug, an American plant breeder, won the Nobel Prize in 1970 for his work in developing improved, high-yield wheat varieties for Mexico. The dramatic improvement in crop diversity and yields experienced over this period was aided by improved management and increased inputs of fertilizer, pesticides, and irrigated water. These improvements helped feed a growing world population and became known as the "Green Revolution."

In recent years, plant breeders have used advanced genetic techniques to perform wide-hybrid crossing of sexually-incompatible plants that could not occur without human intervention. Oats, for example, have been crossed with a number of very distantly-related wild species to increase pest resistance and protein content. Interspecies and intergeneric protoplast fusion, in vitro gene transfer techniques, and somaclonal selection, haploid doubling, induction of polyploidy, and embryo rescue on artificial growth media are all routinely employed by plant breeders to produce viable wide genetic crosses. In addition, plant breeders have used chemical and physical mutagenesis—a highly uncontrolled process—to produce a wide variety of genetic mutants from which they select plants with superior traits. These genetic modification methods have permitted hybridization between plants of the same species, different species, and even different genera to create improved varieties of many plants, including corn, oats, potato, rice, tomato, and wheat, among others.[8]

The development of, and the increasing reliance on, new plant varieties has led to the virtual disappearance of older varieties that could serve usefully as sources of germplasm for future crop improvement and environmental restoration. Therefore, USDA maintains the National Plant Germplasm System, which contains over 400,000 lines and varieties of plants no longer in use or never grown commercially, to provide gene pools for future breeding programs. These plant lines and older varieties may contain genes that could be beneficial in improving the genetic variation of existing or future varieties. They are preserved by USDA as an irreplaceable genetic resource.

The Advent of Agricultural Biotechnology

[7] The double-cross involves producing two single-cross hybrids from four inbred lines, which are then crossed to produce one "double-crossed" hybrid.
[8] For a detailed discussion of the techniques used by breeders to improve crop plants, see: Goodman *et al.*, 1987.

Despite advances in our understanding of plant heredity, traditional cross-breeding relies largely on sexual hybridization and remains a time consuming process that can take 15 years or more before a crop is ready for the market. Traditional breeding is hit-or-miss due to the uncontrolled recombination of tens of thousands of genes producing both desirable and undesirable traits. Also, the constraints imposed by sexual compatibility deny plant breeders access to a diverse range of genetic material, severely limiting the ability to improve crops through traditional means.

In 1905, Sir Roland Biffen's experiments with two varieties of wheat demonstrated that resistance to stem rust fungus was inherited. This led to further attempts by plant breeders to develop pest-resistant strains of other crop plants. However, breeders soon were confronted with the fact that the gene for a desired trait may not always be available in a sexually-compatible plant, so no amount of cross-breeding will yield an improved strain. And even where a desirable gene is available, it may be linked unalterably to another trait that is undesirable (*e.g.*, a fruit with bitter taste). Thus, plant breeders have long sought new technologies to increase the diversity of genes for pest resistance and other traits that could be used to improve plants.

With the development of biotechnology and rDNA techniques, plant breeders now possess the tools to introduce select, useful genes from a wide variety of sources into plants to express specific, desirable traits. Current methods of gene insertion include using a "disarmed" (or benign) plasmid from the plant pathogen *Agrobacterium tumefaciens* as a vector,[9] DNA-coated metal microprojectiles, and direct uptake of DNA by protoplasts of plant cells.[10] Many other promising techniques are under development.

The main advantage of using rDNA technology is that, unlike hybridization, it permits the transfer of specific, well-characterized genes from the source organism to a target plant. The precision of rDNA technology is a vast improvement over traditional cross-breeding, which involves the transfer of all the genes from each parent, requiring repeated rounds of crossing and back-crossing over several generations to produce the desired combination of traits. Using biotechnology, usually only one or two progeny generations are needed to complete the gene transfer.

Gene transfer techniques also are being used increasingly to move genes among plants that could be hybridized using traditional methods and to control, increase, or turn off specific functions within a plant. The greater precision of these techniques will cut significantly the time and cost necessary to bring an improved variety to market.

Once the desired combination of genes has been produced, the process of variety development and scale-up is very much the same regardless of the method used to combine the genes. Thus,

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[9] The bacteria *A. tumefaciens* is the cause of crown gall disease, which produces tumor-like growths on the stems of susceptible plants. Work in the 1970s showed that tumor-inducing genes of *A. tumefaciens* were transferred to the plant via the bacteria's plasmid. Techniques were later developed to locate and then remove the tumor-inducing genes, transforming the plasmid into a useful tool for recombining DNA. For a detailed discussion of the research that led to the development of bioengineered seeds, see: NRC, 1998.

[10] Using these techniques, very few genes actually are transferred. Therefore, "markers" are used to identify and recover those cells or tissues in which the gene transfer has been successful. Antibiotic resistance genes commonly are used for this purpose.

the plant lines under consideration for release as new varieties must still be tested under field conditions at multiple sites over several years to assure that performance will be up to expectations and to reveal any unexpected weaknesses. Most new varieties are subjected to 50 or more site-years (sites _ years) of performance testing before being selected for seed production and farm use.

Applications of rDNA technology already have had a profound impact in biomedical research and human medicine. For example, in 1978, Genentech began using this technology to create bioengineered bacteria to produce human insulin, a product that has replaced bovine and porcine insulin for many diabetics. Other biotechnology products include tissue plasminogen activator for treatment of heart-attack patients, powerful growth factors used in bone marrow transplants, a hepatitis B vaccine, interferon used to attack viruses and stimulate immune response, and diagnostic tests that are keeping America's blood supply safe.

Biotechnology has been used widely in food processing. Chymosin (also called rennin) is an enzyme used to clot milk and produce cheese. In the past, processors obtained chymosin from rennet, a preparation scraped from the fourth stomach of milk-fed calves. Today, the enzyme is purified from a bacterium that has been genetically-altered to produce it. The chymosin obtained in this process is structurally identical to the naturally-occurring form. About 60 percent of the hard cheese produced in the United States is made with chymosin from genetically-modified bacteria.

The first effort at marketing a crop food modified through biotechnology occurred in the 1989, when Calgene Corporation initiated discussions with FDA regarding its Flavr Savr tomato, engineered to provide extended shelf-life. In this case, the plant's own gene for production of an enzyme that naturally softens the fruit was disabled by inserting it "backwards" (antisense) within the tomato genome. Approved by FDA in 1994 and well received by curious consumers, the Flavr Savr tomato was not a commercial success for reasons unrelated to the product. The British company Zeneca, however, achieved greater success marketing a genetically-modified tomato used in making tomato paste for sale in the United Kingdom.

Crops designed to resist pests and viruses or to tolerate certain broad-spectrum herbicides make up the bulk of the first generation of commercially-viable biotechnology crops. "Bt" corn, potato, and cotton each incorporates select genes from the widely-used biological control agent *Bacillus thuringiensis* to resist targeted insect pests. *B. thuringiensis* is a soil microbe that produces proteins—delta-endotoxins—that are selectively toxic to certain kinds of insects but harmless to other insects, humans, and animals.[11] Bt corn, for example, produces the endotoxin in the corn, enabling the plant to ward off the European corn borer, a pest that costs U.S. corn growers over $1 billion each year. Bt potatoes and Bt cotton have been engineered to resist the Colorado potato beetle and the pink boll worm, respectively. These crops are widely planted by American farmers and have resulted in substantial savings.

Many commercially-important plants, such as potato, squash, cucumber, watermelon, and papaya, have been modified to protect themselves against viral infection simply by introducing virus genes that produce viral coat proteins. Viral coat proteins are components of the outer wall

[11] Spray insecticides derived from *B. thuringiensis* are used widely in organic farming.

that enclose the genetic material of a virus. Plants modified to produce viral coat proteins resist viruses through a mechanism known as cross-protection, which is somewhat analogous to immunization. Farmers and consumers have gained from substantial savings by reducing chemical inputs normally required to control virus-carrying insects.

Soybeans and other plants have been modified to tolerate broad-spectrum herbicides used by farmers to control weeds. The most common is the "Roundup® Ready" soybean, a plant that has been designed to tolerate Roundup Herbicide (glyphosate), developed and produced by Monsanto. Unlike many other herbicides, glyphosate has low toxicity, is safe for humans and animals, and degrades quickly in the soil. Other plants have been developed to withstand glufosinate, produced by AgrEvo, and bromoxynil, produced by Rhône-Poulenc Rorer. In the United States, the use of herbicide-tolerant crops has reduced herbicide use and allowed farmers to adopt no-till farming methods that minimize soil erosion and moisture loss.

In addition to pest resistance and herbicide tolerance, other traits are being added to crop plants that will allow them to withstand drought, freezing temperatures, and salt toxicity. Future advances offer the promise of an impressive array of new and useful products that will improve crop yield and quality, provide better nutrition, deliver needed vaccines and medicines, produce more desirable fats and oil, extend the shelf life of fruits and vegetables, lower food costs, and create renewable non-food products that can reduce reliance on nonrenewable resources. Development of these and other new varieties of plants is underway and will open up entirely new markets to farmers and provide enhanced food products to consumers.

Agricultural biotechnology is a thriving industry, and many U.S. farmers have readily adopted this new technology. It is estimated that in 1998, 26 percent of the corn, 43 percent of the cotton, 4 percent of the potato, and 26 percent of the soybean crop in the United States was planted with varieties modified using agricultural biotechnology (Gianessi and Carpenter, 1999).

PLANT GENOME RESEARCH

The plant genome program provides much of the basic research into plant genetics that will be used to produce future products. The United States Government became directly involved in plant genome research in 1989, with the initiation of the Multinational Coordinated *Arabidopsis thaliana* Genome Research Program, supported jointly by NSF, the Department of Energy (DOE), USDA, and the National Institutes of Health (NIH). The project started out with two ambitious goals: (1) to determine the complete sequence of *Arabidopsis thaliana*, a member of the mustard family; and (2) to use this information to understand the physiology, biochemistry, growth, and developmental processes of flowering plants at the molecular level.

The value of *Arabidopsis* in genetics research was first recognized by the German Friedrich Laibach, who published a paper on its chromosomes in 1907 and later promoted its usefulness as a research tool in 1943. Though not a crop plant, *Arabidopsis*—a simple, flowering mustard plant usually described as a weed—nonetheless makes an excellent subject for plant genome research. It has a simple genome (about a fifth the size of the sorghum genome and a hundredth the size of the wheat genome), a short generation time (six weeks), and several plants can be grown in a square centimeter. Moreover, mutations can be induced easily, providing valuable

insights into the plant's genome. In short, *Arabidopsis* is both relatively simple and representative, making it suitable as a model for a whole classification of flowering plants.[12]

The goals of the plant genome program were considered quite risky in 1990 when they were developed "because the biological and computing technology was not yet available to accomplish this feat" (Clutter, 1999). By 1996, technology had matured to the point that it was possible to begin the total sequencing of the *Arabidopsis* genome. Rapid progress was made, and in December 1999, researchers in the United States and England announced the sequencing of two complete chromosomes, or about 30 percent of the estimated 26,000 genes in *Arabidopsis*.[13] Sequencing the entire genome should be completed by the end of 2000.

In 1997, an Interagency Working Group (IWG) on plant genomics was established under the auspices of the Office of Science and Technology Policy (OSTP). Participants in this working group include representatives from NSF, USDA, DOE, NIH, the Office of Management and Budget, and the Office of Science and Technology Policy (OSTP). IWG developed a five-year strategic plan for the National Plant Genome Initiative (NPGI) with the ultimate goal of understanding the structure and function of every gene. Using DNA microarray analysis and other advanced techniques, scientists will be able to determine the expression of all the genes in an organism.

As part of its five-year plan, the IWG set the following goals for NPGI:

- Complete the sequencing of the model plant species, *Arabidopsis*;
- Participate in an international effort to sequence rice;
- Develop the biological tools to study complex plant genomes, such as corn, wheat, soybean, and cotton;
- Increase our knowledge of gene structure and function of important plant processes;
- Develop appropriate data handling and analysis capabilities; and
- Ensure that this new information will be accessible to the broader community of plant biologists and maximize the training opportunities that will arise from the initiative.

The Plant Genome Research Program at NSF was established in 1998 as part of the NPGI. Since its inception, NSF support has focused on two areas: (1) structural and functional genomics and (2) strengthening the research infrastructure. In addition to the work on *Arabidopsis*, U.S. participation in the international rice genome sequencing project began with support provided by USDA, DOE, and NSF in Fiscal Year 1999. For Fiscal Year 2000, NSF plans to spend $79.5 million on plant genome research and for Fiscal Year 2001 requested an additional $22.5 million (to $102 million).

OVERSIGHT OF AGRICULTURAL BIOTECHNOLOGY

Oversight of agricultural biotechnology includes both regulatory and nonregulatory mechanisms that have been developed over many years for crop plants. The following discussion of

[12] For more on *Arabidopsis*, see: Meinke *et al.*, 1998.

[13] *Arabidopsis* contains an estimated 130 million base pairs of DNA. In contrast, the human genome is estimated to contain more than 100,000 genes with three billion base pairs of DNA.

regulatory oversight that follows concentrates on the federal agencies, but it should be pointed out that state regulatory agencies also have an important, if subordinate, oversight function.

The Responsibilities of the Plant Breeder

Today, plant breeding programs are conducted by State Agricultural Experiment Stations (SAES), Land Grant colleges and universities, USDA Agricultural Research Service stations (usually in cooperation with SAES), and private companies. Based on agronomic need, crop development teams decide on a trait to be introduced to a variety of plant. If such a trait is available among the many genetic resources available, a decision is made on how to impart it to the crop. This can be done through sexual hybridization, various wide-cross techniques, or rDNA technology.

Regardless of the method, once the genetic transformation has been made, offspring of the plant are grown and observed. This process ensures genetic stability by establishing that the added trait is permanent and predictable and is expressed under varying conditions (OECD, 1993a). After producing and observing subsequent generations and eliminating plants with undesirable traits, the breeder selects a few plant lines for large-scale testing.

By the time a new variety of plant is ready for release or commercialization, it has undergone significant review and testing. The plant breeder is responsible for considering agronomic and ecological factors during the development phase, including yielding potential, reproductive stability, uniformity of traits, weediness, vulnerability to attack by pests, sensitivity to environmental stresses, and other factors. When developing varieties with unusual risks, the breeder will adopt evaluation methods designed to assess and manage the risk. If the plant is to be used as a food, the breeder also is responsible for evaluating the food product for toxins and allergens.

After extensive performance tests and reviews, a new variety may be released. The Association of Official Seed Certifying Agencies has set up variety review boards for many important crop plants. Breeders are not required to submit their new varieties to these boards, but for seed crops eligible for protection under the Plant Variety Protection Act, such protection is exercised only through the seed certification process. In applying for certification, the breeder must submit a detailed description and broad array of other information about the new plant variety.

Peer-reviewed journals also are used to register the release of plants either as a new variety, germplasm, or genetic stock. The scientific societies that publish these journals establish their own specific criteria and protocols, but in all cases the published information, which is in the public domain, provides valuable data on the new variety.

Both certification and peer review have been effective in providing non-regulatory oversight. It is important to note that these procedures are not required by law but rather have been developed voluntarily by breeders and growers over decades based on our increasing knowledge and experience. As the techniques to develop new plant varieties become more advanced, the procedures used by plant breeders are expected to keep pace through the evolution of standard best practices informed by increased knowledge. "It is a natural progression of science," noted

11 professional scientific societies, "to adopt ever-better techniques and establish ever-higher standards of performance in research and development" (IFT *et al.*, 1996).

Coordinated Framework and Statement on Scope

The development of rDNA techniques in the 1970s led to concerns about the potential hazards associated with the technology. In 1974, the NIH Recombinant DNA Advisory Committee published guidelines for laboratory research using biotechnology.[14] NIH remained the primary federal body that reviewed and monitored rDNA research until 1986, when OSTP published the "Coordinated Framework for Regulation of Biotechnology" (Coordinated Framework) for the White House Domestic Policy Council Working Group on Biotechnology (OSTP, 1986).[15]

The Coordinated Framework provided a regulatory roadmap relevant to biotechnology research and products, and it identified possible gaps in oversight. Under the Coordinated Framework, new products developed through biotechnology would be regulated "in essentially the same manner for safety and efficacy as products obtained by other techniques" and would be regulated under authority granted under existing federal statutes and regulations. The framework also identified lead agencies to coordinate activities where jurisdiction overlapped, and it explained the proper allocation and coordination of regulatory oversight under various statutes and among relevant agencies.

The regulation of plants and foods created through agricultural biotechnology is handled by three federal agencies: USDA, which is responsible for ensuring that new varieties are safe to grow; EPA, which is responsible for ensuring that new pest-resistant varieties are safe to grow and consume; and FDA, which is responsible for ensuring that new varieties are safe to consume.[16]

While the Coordinated Framework took into account the different statutory bases for regulation among the agencies, it also emphasized that common principles should govern decisions concerning the exercise of discretionary regulatory authority. Under the auspices of a White House Working Group, the involved Federal agencies—including USDA, EPA, and FDA—agreed to a common statement on federal oversight within the scope of statutory authority. This "Statement on Scope" was published by OSTP in 1992 and addressed how oversight authority should be exercised in situations "in which a statute leaves the implementing agency latitude for discretion" (OSTP, 1992).[17]

The Statement on Scope lays out a scientific, risk-based approach as the proper basis for regulatory oversight. It establishes two main criteria for regulation of biotechnology products: (1) oversight authority should be exercised only where there is evidence that the "risk posed by the introduction is unreasonable"; and (2) regulatory oversight "should focus on the characteristics and risks of the biotechnology product—not the process by which it was created."

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[14] It is worth noting that within a few years, NIH deemed that there was sufficient scientific knowledge regarding the safety of rDNA techniques to relax these guidelines substantially.

[15] OSTP published a proposed "Coordinated Framework" in the *Federal Register* on December 31, 1984.

[16] In addition, the Department of Labor's Occupational Safety and Health Administration was given responsibility for the safety and health of biotechnology workers and NIH was given responsibility for the safety of rDNA research.

[17] OSTP published a proposed "Statement on Scope" in the *Federal Register* on July 31, 1990.

In setting these guidelines, it was expected that the agencies would implement them "in a manner appropriate to each statutory framework" and "consistent with the risk-based principles" set out in the document (OSTP, 1992).

U.S. Department of Agriculture

Under authority found in the Federal Plant Pest Act and the Plant Quarantine Act, USDA's APHIS issues field-test permits for new plants that have the potential to create pest problems in domestic agriculture. APHIS regulations provide procedures for obtaining a permit or for providing notification prior to importing, moving interstate, or releasing a "regulated article" in the United States.

Regulated articles are defined by APHIS as plants or microorganisms that are, or are believed to be, plant pests or are produced using plant pests. Under the Coordinated Framework, APHIS is responsible for regulating bioengineered agricultural plants produced using a pathogenic source organism. Genes commonly are introduced into plants using the disarmed plasmid of *A. tumefaciens* (which in nature causes plant gall) as the vector, and their expression is promoted by a DNA regulatory sequence from the cauliflower mosaic virus (another plant pest). Consequently, regulated-article status has been applied to most of the genetically-modified plants that have been developed to date.

APHIS regulations provide procedures for obtaining a permit for field testing. To receive a permit, the plant breeder must provide information pertaining to how the plant was developed and the control measures that will be taken during the trials, including field design, monitoring, and reporting requirements. If, after a review of the disclosure information submitted by the plant developer, the agency reaches a "finding of no significant impact," a field test permit is issued.

The growing familiarity with rDNA-altered crops led APHIS to introduce in 1993, and later expand in 1997, an expedited procedure for approving field testing of plants developed using rDNA techniques. Instead of submitting a formal application for a permit, plant breeders wanting to field test plants that meet certain eligibility requirements and performance standards need only submit a "notification" letter to the Agency. The notification must include a description of the gene, the characteristics of the plant, and the location of the proposed tests. As part of this procedure, APHIS then notifies the department of agriculture in the state where the proposed trials will be conducted.

After several years of field trials, the plant breeder may petition APHIS to release its new plant variety from regulatory requirements through a determination of "nonregulated status." Before a determination to deregulate is made, USDA requires data on the rationale for development of the plant, the system used to transform the genome, the donor genes and regulatory sequences used, genetic analysis and agronomic performance, the environmental consequences of introduction, and the adverse consequences of introduction.[18] If the petitioner has demonstrated that its new plant variety is free from risk under applicable regulations, APHIS will issue a determination of

[18] APHIS maintains an extensive database, accessible to the public, describing the characteristics and the results of the field tests for each regulated plant that goes through the approval process.

nonregulated status. As part of its review, APHIS performs and environmental assessment under National Environmental Policy Act requirements.

Once APHIS confers nonregulated status, unregulated interstate movement and release of the new plant is allowed. If, however, APHIS determines that the new variety poses an environmental risk—for example, if the plant demonstrates a significant potential to outcross with wild relatives and create problems—it has the authority to suspend the field trials and halt further development of the plant.

Since 1987, APHIS has processed more that 5,000 permits and notifications for field testing at over 22,000 sites and nearly 50 petitions for deregulation. Of the 44 different types of plants modified using rDNA techniques, field testing has occurred for varieties altered for herbicide tolerance (28%), insect resistance (24%), product quality (19%), virus resistance (10%), agronomic properties (6%), fungal resistance (5%), and other properties, including bacterial resistance (8%). In no instance has a biotech plant approved for field testing by USDA created an environmental hazard or exhibited any unpredictable or unusual behavior compared to similar crops modified using conventional breeding methods (McCammon, 1999).

Organic Rule. The debate over agricultural biotechnology also has spilled over in the discussion of what should or should not be labeled as an organic food. The Organic Foods Production Act of 1990, part of the 1990 Farm Bill, requires USDA to develop national standards for organically-grown foods and to ensure that foods labeled "organic" are grown consistent with these requirements. On March 7, 2000, USDA announced a new proposal for organic standards. Under the proposed rules, foods derived from crop plants developed using biotechnology would not qualify for the organic label, even if grown in conformity with organic standards.

Environmental Protection Agency

EPA's Office of Pesticides Programs, Biopesticides and Pollution Prevention Division, regulates and registers "plant pesticides" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).[19] Bt corn is perhaps the most well known example of a plant modified to produce its own pesticide.

In November 1994, EPA issued a new proposal detailing how it would regulate plant pesticides to meet the requirements of FIFRA and FFDCA. This proposal is now in the final stages of the rule-making process and is expected to be concluded sometime in 2000.

While the proposed plant pesticide rule has been moving through the review and public comment process, EPA has been using approval and registration guidelines that have been established for testing chemical, microbial, and biochemical pesticides. The Agency also is required under FFDCA to establish a safe level of pesticide residue in foods, known as a "tolerance."

Before submitting an application for field-test approval and registration, the plant breeder consults with EPA scientific staff to decide upon the data requirements that will support the

[19] EPA also regulates bioengineered microorganisms under the Toxic Substances Control Act.

Experimental Use Permit (EUP). The studies done under the EUP are used to support the application for registration.

EPA's registration requirements include data on product characterization, toxicology, effects on non-target organisms, exposure, and environmental fate. Data on product characterization includes the source of the gene, how the gene is expressed, the nature of the pesticidal substance produced, modifications to the introduced trait as compared to that trait in nature, and the biology of the recipient plant. For toxicology, acute oral toxicity of the pesticidal substances administered to mice has been required. EPA also requires a digestibility test to determine the amount of time it takes for the protein to break down in gastric and intestinal fluids. Allergenicity of the substance also must be considered. For ecological effects, EPA examines the exposure and toxicity of the plant-pesticide to non-target organisms, such as wildlife and beneficial insects. EPA also has evaluated the degradation rates of the proteins in soil and plant residues (Anderson, 1999).

EPA registered its first plant pesticide in March 1995. Since then, EPA has registered and granted tolerance exemptions to 12 plant pesticides. Six of these products are for Bt toxins produced in corn, potato, and cotton, and four are for viral coat proteins that have been transferred to potato, cucumber, watermelon, and papaya. EPA also approved and exempted from tolerance requirements a protein from the potato leaf roll virus and the potato virus Y. Dr. Anderson testified that "EPA . . . has found no documented case of environmental harm caused by a plant-pesticide produced through biotechnology."

Insect Resistance Management. Consumer groups and organic farmers have expressed concern that widespread use of plants engineered for specific types of pest resistance—particularly those manipulated to express Bt toxins, which have been used widely in a spray formulation by organic farmers—could accelerate the development of pesticide-resistant insects. To address this issue, EPA now makes insect resistance management plans a central part of its regulatory decisions on plant pesticides, and seed companies require purchasers of their seeds to implement such plans. These agreements require farmers to establish "refugia" of non-modified plants that can nurture populations of wild type pests. The view is that refugia will help maintain the genetic basis of susceptibility of the target pest species and delay the onset of genetic resistance.[20]

On April 19, 1999, a biotechnology industry group[21] submitted an insect resistance management plan to EPA, and on January 14, 2000, EPA announced new measures for resistance management in Bt corn for the 2000 growing season that mirrored the industry plan. It directs registrants to ensure that growers maintain refugia of at least 20 percent non-Bt corn—50 percent in areas where cotton is grown. The agency also requires increased monitoring and restrictions on planting Bt corn in certain areas.

Proposed Plant Pesticide Rule. In November 1994, EPA published in the *Federal Register* its proposed regulations outlining how it would determine that new varieties of pest-resistant plants

[20] Refugia of non-Bt crops work by ensuring that pests susceptible to Bt toxins are available to mate with any resistant strains that may emerge within an insect population exposed to crops modified to produce Bt toxins.

[21] This group was composed of Novartis, Pioneer Hi-Bred International, Mycogen Seeds/Dow AgroSciences, and Monsanto in conjunction with the National Corn Growers Association.

would meet the requirements of FIFRA and FFDCA. A plant pesticide is defined by EPA as a "pesticidal substance that is produced in a living plant and the genetic material necessary for the production of the substance, where the substance is intended for use in the living plant" (EPA, 1994).

The Agency states that the purpose of the new proposal is to focus regulatory oversight on plant-pesticides that create novel exposures or operate with a more toxic mode of action. It would: (1) clarify the regulatory status of plants and plant-pesticides under FIFRA and FFDCA; (2) specify that EPA regulates the plant-pesticide rather than the plant itself; and (3) describe the categories of products subject to, and exempt from, regulation (Anderson, 1999). Exemptions would be made for plant pesticides derived from plants related to the recipient plant,[22] those that act by affecting the plant,[23] and those based on a coat protein from a plant virus (EPA, 1994).[24]

According to Dr. Anderson, "The primary focus of the new regulations is to separate out and exempt from regulation those compounds the Agency believes have a low probability of risk and instead concentrate on plant-pesticides that present new dietary and/or environmental exposures. For example, plant-pesticides introduced from unrelated species of plants, bacterium or virus, insects, etc." The focus of EPA's proposed rules clearly would be on new pest-resistant varieties produced using biotechnology. It has been argued that by targeting the *process* by which the a new plant is produced, EPA is departing from the risk-based scientific principle that regulations should focus on a plant's characteristics, not its method of production (IFT *et al.*, 1996; Huttner, 1999).

Food and Drug Administration

Often overlooked in the debate over food safety is that it is the legal responsibility of the food producer to ensure the safety of foods they offer consumers. In addition, food producers are subject to Federal, State, and local regulations. At the Federal level, FFDCA gives FDA a broad range of legal authority and regulatory tools to ensure the safety of whole foods. It has the authority to require premarket review and approval in cases where protection of public health is required, such as when a substance is added intentionally to a food and there are questions about its safety. FDA also has postmarket authority to remove a food product from commerce and sanction those marketing the food if it poses a risk to public health. The complex array of criminal and civil sanctions, including tort and contractual remedies, available to governments and private parties provides producers with every incentive to bring safe, wholesome foods to market.

Foods produced through biotechnology must adhere to the same safety standards that apply to traditionally-produced foods under FFDCA. In 1992, FDA published in the *Federal Register* a Statement of Policy on its approach to regulation of foods derived from genetically-modified

[22] Among the options for exemption are plant pesticides derived from plants that are sexual compatible, within the same genus (though not necessarily sexually compatible), or both sexually compatible or within the same genus (EPA, 1994).

[23] An example includes plants altered to grow larger leaf "hairs" (trichomes) to prevent insects such as aphids from feeding on them.

[24] EPA's preferred option is to exempt all viral coat proteins; a second option is to exempt only those coat proteins in plants with a low probability of outcrossing to wild relatives (EPA, 1994).

plants (FDA, 1992).[25] It is important to note that these rules apply equally to plant-derived foods produced using traditional breeding techniques as well as biotechnology.[26] FDA's guidelines provide a risk-based "decision tree" to guide plant breeders and food manufacturers through issues critical to ensuring the safety, nutritional value, and wholesomeness of new genetically-altered foods. This approach is based on many decades of FDA experience dealing with a complex array of new fruits, vegetables, and grains that have been modified using conventional methods and safely introduced into the food supply without the agency's intervention.

Guided by the decision tree, plant developers and food manufacturers conduct a safety assessment of the new food, paying particular attention to changes in naturally-occurring or introduced toxicants and allergens, nutrient levels, and fat, oil, or modified carbohydrate content, as well as the introduction of new substances that do not have a history of safe use. Where significant alterations are found, formal FDA review and approval are required. FDA requires approval and labeling only where unexpected effects are produced (such as allergens or toxins are introduced), the nutrients in or composition of the product is substantially different from traditional edible varieties, or pharmaceuticals are present.

Food producers are not required to seek FDA pre-market approval or to apply a special label, for a new variety of food if it is substantially equivalent to existing varieties already on the market. They are, however, encouraged to consult with the agency in considering safety issues. If a new food contains a "food additive," FDA would not require pre-market approval or special labeling if it could be shown that the additive is "generally recognized as safe" (GRAS). An ingredient with a long history of safe use, for example, would be considered GRAS. Other new ingredients, however, would require a submission of a GRAS petition to FDA that would be reviewed in a way similar to a FDA review of a new food additive.

Without exception biotech companies have participated in a "voluntary consultation" with FDA before bringing a new biotech food to market. During these consultations, companies are expected to provide FDA with data on the agronomic and quality attributes of the plant, genetic analysis of the modification and stability of expected genomic traits, evaluation of the safety of newly introduced proteins (*e.g.*, for allergenicity), and chemical analyses of important toxicants and nutrients. When all safety and regulatory issues have been resolved, FDA provides written notification to the company.

When asked if FDA was aware of any examples of a biotech food causing a human health problem, Dr. Maryanski responded: "No, FDA is not aware of any such case" (Maryanski, 1999). To date, the vast majority of foods developed using rDNA techniques have not required pre-market approval, and none has required labeling.

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[25] For a good summary of this document, see: Kessler *et al.* 1992.

[26] FDA's Statement of Policy defines genetic modification as the "alteration of the genotype of a plant using any technique, new or traditional."

FINDINGS

The testimony and other materials and documents made available to the Subcommittee lead to the following findings.

PLANT GENOME RESEARCH

Finding: The plant genome program represents a sound use of federal research funding.

Understanding *Arabidopsis*, the relatively simple mustard plant that is the focus of NSF's Plant Genome Research Program, promises to unlock a wealth of understanding about how other plants work. As Dr. Ryals noted in his testimony, the main rate-limiting step in agricultural biotechnology is gene discovery (Ryals, 1999). Future breakthroughs in plant genomics may very well rest upon the successes of the *Arabidopsis* project and other federally-funded research initiatives that involve corn, rice, tomato, and other plants.

The federal government has supported plant genome research directly since the initiation of the Multinational Coordinated *Arabidopsis thaliana* Genome Research Program in 1989. The Project began with the ambitious goals of determining the complete sequence of the *Arabidopsis* genome and developing an understanding of the physiology, biochemistry, growth, and developmental processes of flowering plants at the molecular level.

In her testimony, Dr. Clutter highlighted a number of practical applications that have resulted from *Arabidopsis* research, including:

- Demonstrating that plants can be used to manufacture renewable biodegradable plastics in quantities suitable for industrial production.
- Elucidating complex genetic pathways by which a plant produces various oils. These genes have been used to modify canola and soybeans to produce oils of improved nutritional value; the same genes can be used to produce industrial lubricants and fuels.
- Identifying a gene that confers tolerance to sulfonylurea, a commonly used herbicide. This discovery is being used to develop crops suitable for no-till agriculture.
- Showing that plants can be modified to clean up heavy metals in the environment, such as mercury and cadmium.
- Discovering how plants take up iron and other micronutrients in the soil. This information is immediately applicable in producing crops that contain high iron and other essential mineral nutrients.
- Developing plants naturally fortified with vitamins, opening up a new area of study, "nutritional genomics."

The *Arabidopsis* project also has provided insight into the nature of complex genetic traits. In his testimony, Dr. Larkins commented that, in addition to aiding plant breeders in creating new varieties using biotechnology, "the knowledge gained from understanding the molecular basis of such traits can be applied to crop improvement through conventional breeding programs" (Larkins, 1999).

With the rapidly growing amounts of genetic information being discovered comes a serious need for new information technologies to catalogue and mine the data. The data requirements of the *Arabidopsis* program has led to a considerable investment in the field of bioinformatics—a merging of information technology, biotechnology, and agricultural sciences. The *Arabidopsis* Information Resource (TAIR) project, for example, accessible to researchers worldwide over the Internet, will include all information about the *Arabidopsis* genome project.[27] The USDA Agricultural Research Service also funds a Plant Genome Database.[28] In addition to these Federal databases, the National Center for Genome Resources, a non-profit research organization in Santa Fe, New Mexico, also supplies bioinformatics resources to assist researchers both in identifying problems that could be solved by genetic strategies and in developing new plant varieties (Joseph, 1999).

As a result of these efforts, researchers are well on their way towards fulfilling the first goal of sequencing the entire *Arabidopsis* genome. Dr. Clutter testified that work on the second goal—determining the function of the plant's estimated 25,000 genes—begins with the initiation of NSF's proposed "2010 Project." "At present," said Dr. Keegstra, "scientists are able to determine experimentally, or predict by comparison with other known genes, the function of just over half of the identified genes. . . This large gap in our knowledge represents a major challenge for biologists, and addressing this problem for *Arabidopsis* is the goal" (Keegstra, 1999). Improving our understanding of the function of all the genes in the *Arabidopsis* genome will help plant breeders and researchers create ever-larger numbers of new and beneficial cultivars.

Publicly-funded research data are mined actively by agricultural companies. U.S. Patent Office records reveal that prior to 1990, just one patent for *Arabidopsis*-based discoveries was issued. The current total of 622 patents represents an exponential increase in patent grants in for *Arabidopsis*-related innovations over the last 10 years (Clutter, 1999). Dr. Kennedy also described USDA efforts at technology transfer through Cooperative Research and Development Agreements. The Cooperative Extension Service is another route used for technology transfer (Kennedy, 1999).

Ensuring that the results of genome research finds its way to market still remains a challenge. Dr. Huttner commented that "there is a substantial gap between the basic research bench and...end users," a gap similar to that faced by the biomedical sector in its infancy and one ultimately filled by small business. "Small companies tap into the tremendous creativity found in university faculty and students, whereas big companies have extensive in-house research operations, tend to be more risk averse, and often discount advances achieved in publicly-funded institutions." She argued that basic research results are transferred more easily to small start-ups willing to take risks big agribusiness may not. This transfer could be furthered by the creation of NSF- and USDA-funded research centers—public-private partnerships that could combine basic research in genomics with plant development for small, specialty markets.

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[27] TAIR replaces the *Arabidopsis thaliana* Database (AtDB).

[28] This database is comprised of a Stock Center Database, which provides researchers with information on genetic variations through the Germplasm Research Information Network; the Genome Mapping Database, which includes physical and genetic map types of many agricultural plant species and some model systems from non-agricultural species; and DNA Sequences, which are placed into the widely used GenBank/GenInfo/European Molecular Biology Laboratories and DNA Databand of Japan.

CHEMICAL INPUTS

Finding: The current generation of pest-resistant and herbicide-tolerant agricultural plants produced using biotechnology has reduced chemical inputs and improved yields for American farmers. Future adoption of new varieties will continue this trend and will solve intractable pest problems, help protect the environment, and lower costs to consumers.

Agricultural producers must defend their crops from a variety of plant pests and diseases. Insects such as the European corn borer and the Colorado potato beetle can inflict terrible damage on crops, affecting yields significantly. Pressures from weeds, disease, and weather can further hinder crop production.

Traditionally, producers have relied upon a variety of different "inputs," such as applications of herbicides, insecticides, fertilizers, and irrigated water to protect crops and boost production. Each of these inputs adds—sometimes greatly—to the cost of the product, but they are necessary investments to prevent crop losses caused by infestation, drought, or other circumstances. In addition to the financial costs of inputs, environmental costs may be exacted as well. Thus, reducing the use of chemicals without reducing crop yield or quality is a goal that will deliver both economic and environmental benefits.[29]

The recent experience with biotech crops indicates that they significantly reduce input use and costs. Pest-resistant corn and herbicide-tolerant soybeans already are used widely in the United States, reducing pesticide and herbicide usage and, correspondingly, decreasing costs to producers and increasing farm income (USDA 1999). In testimony submitted to the Subcommittee, Dr. Prakash estimated that biotech crops saved United States and Canadian producers nearly $500 million in 1998, and are projected to save $6 billion by 2005 (Prakash, 1999).

Pest-Resistant Plants. Pest-resistant Bt cotton varieties have been notably effective in reducing chemical insecticide inputs and lowering costs to producers, particularly cotton growers. By introducing Bt genes into varieties of cotton, they have become biologically protected from three common and costly pests: tobacco budworm, cotton bollworm, and pink bollworm. In 1995, resistant budworms in Alabama caused yield losses of nearly 30 percent. In the absence of Bt crops, producers rely upon pyrethroid insecticides to control these pests. However, the tobacco budworm has developed a resistance to pyrethriod insecticides, severely limiting their effectiveness (Gianessi and Carpenter 1999).

Mr. Gianessi and Ms. Carpenter reported that producers who adopted Bt varieties controlled all three target pests: "USDA pesticide use data show a reduction of 2 million pounds of the insecticides that are recommended for the control of these insects since the introduction of Bt cotton varieties." As a result, they expect growers will experience increased yields using Bt varieties compared to conventional varieties, resulting in increased returns of approximately $40 per acre. Some of these gains are being realized today. USDA's Economic Research Service

[29] Biotechnology also has the potential to reduce chemical inputs on lawns and golf courses, which account for a significant portion of pesticide use.

(ERS), for example, found that "adopting Bt cotton had significantly increased yields and variable profits in 1997" (ERS, 1999b).

The situation with respect to the use Bt corn is somewhat different, and it is often cited by critics of biotechnology as an example of a bioengineered crop that has not met expectations. For example, Dr. Goldburg, citing recent USDA data, argued that "Bt corn largely supplements rather than substitutes for insecticide use on field corn—the type of corn planted on the vast majority of U.S. corn acreage. Across the midwestern corn belt, only about 5% of corn acreage is treated with insecticides for the European corn borer, the primary target pest of Bt corn. Thus, for the most part, farmers planting Bt corn are not substituting Bt genes for conventional chemical insecticides. . . [I]nsecticide use against European corn borers in 1997 in the 'Heartland' region of the United States...was only slightly higher on non-Bt corn than on Bt corn" (Goldburg, 1999).[30]

However, Bt varieties are aimed at controlling pests that were previously difficult or impossible to control, not replacing chemical pesticides. Defending corn requires expensive management practices, such as plowing and rotation, as well as chemical pesticides, that may not always work. As Mr. Gianessi and Ms. Carpenter explained, "[D]ue to the difficulty in scouting for this pest and the importance of timing insecticide application before the caterpillar bores into the corn stalk and is protected from insecticides, it is estimated that less than 5 percent of corn field acreage in the U.S. Corn Belt was being treated with insecticides for the European Corn Borer prior to the introduction of Bt corn varieties." As a result, the introduction and adoption of Bt corn varieties may not have a large impact on pesticide usage, but it does have the potential to stem corn losses ranging from 33 million bushels to over 300 million bushels per year.[31]

Herbicide-Tolerant Plants. Herbicide-tolerant crops show promise in reducing herbicide input levels and costs and shifting herbicide use to more environmentally-benign formulations. Farmers growing traditional varieties of soybeans, for example, typically use high levels of more residual herbicides that persist throughout the growing season, with greater environmental risk. Glyphosate—marketed under the brand name Roundup®—is an effective broad-spectrum herbicide that degrades quickly in the soil and has low toxicity. However, because the chemical affects a wide range of plants, including crop plants, it could not be used after planting because it would kill both weeds and crops. Biotechnology has helped farmers solve this problem. "Through the power of genetic engineering," said Dr. Thomashow, "genes have been isolated, modified and transformed back into crop species to make them resistant to the herbicide. This, then, has made it possible for farmers to use the herbicide to kill weeds, but grow healthy crops" (Thomashow, 1999).

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[30] It should be noted that more recent research has shown even greater reduction in insecticide use. An Iowa State University study found that 26 percent of the Midwestern farmers who planted Bt corn in 1998 decreased their insecticide use. The study also noted that 82 percent of farmers said their primary reason for planting Bt corn was to prevent losses from the corn borer, while 27 percent wanted to eliminate the need for insecticide to control the pest (AP, 1999).

[31] Dr. Huttner reported similar results in her testimony, observing that growers using Bt corn varieties in 1998 produced an additional 4.2 bushels per acre and saved 60 million bushels of corn from European corn borer losses—the equivalent of 450,000 acres that would otherwise have been destroyed.

The impact of herbicide-tolerant soybeans has been dramatic. An analysis by USDA's ERS found that in 1997, herbicide treatments for soybeans were significantly lower. "As GMO [genetically-modified organism] adoption increased, use of glyphosate herbicide (such as Roundup®) also increased but use of other synthetic herbicides decreased by a larger amount. The net result was a decrease in the overall pounds of herbicide applied" (ERS, 1999c).

This reduction in herbicide use has brought material benefits to the farmer. Dr. Prakash noted an independent study that estimates the use of Roundup Ready soybeans "saved farmers nearly $30 a hectare because of a 40 percent reduction in herbicide usage, and also increased crop yield due to less competition from weeds" (Prakash, 1999).

Just as significantly, herbicide-tolerant crops enable no-tillage farming, a technique that greatly minimizes moisture loss and soil erosion, a severe problem in many areas of the country. Dr. Cook testified that in his 20 years of research into growing crops without tillage, "I can say unequivocally that the development of Roundup as a tool has been the single greatest tool for moving forward to growing crops with less tillage" (Cook, 1999).

Plant Pathogens. Agricultural biotechnology also is aiding farmers in the fight against other crop infestations. Plant pathologists have spent decades using traditional cross-breeding techniques in an attempt to develop new varieties of commodity crops that are resistant to viruses, fungi, and bacteria, with varied success. Despite decades of focused efforts using traditional breeding methods by USDA, Land Grant colleges, and seed companies, there are many pests for which scientists have not been able to develop pest resistance because the gene for resistance is not found in any sexually-compatible plant. Dr. Cook estimates that resistant varieties have been developed for no more than twenty-five percent of fungal diseases, an even smaller percentage of virus and bacterial diseases, and very few specific insects.

For many stubborn problems, such as soil-borne pathogens, biotechnology may offer the only option. Dr. Cook told the Subcommittee of his work in the root diseases of wheat and barley. He said, "We have been waiting 35 years to have access to genes that we can now put into wheat or barley to have resistance. There have been no genes in the whole pool of germplasm of wheat and barley that I could use for this . . . but we now have the means to bring genes in from natural enemies of some of these pathogens in the same way that Bt has been put into corn."

The Subcommittee also heard testimony about the economic devastation pest epidemics can cause in rural communities. The outbreak of wheat scab in western Minnesota and eastern North Dakota, for example, caused hundreds of millions of dollars in crop losses. Biotechnology will provide researchers with new tools to solve some of the most persistent pest problems in agriculture and help prevent severe economic losses in vulnerable farm communities.

Consumer Benefits and Global Food Production

Finding: The promise of agricultural biotechnology is immense. Advances in this technology will result in crops with a wide range of desirable traits that will directly benefit farmers, consumers, and the environment and increase global food production and quality.

Thomas Jefferson once said, "The greatest service which can be rendered any country is to add a useful plant to its culture." If the testimony presented before the Subcommittee is representative, then in the coming decade the Nation and the world can look forward to the addition of many new plants producing higher yields and possessing desirable traits because of plant genomics and agricultural biotechnology.

Current applications of agricultural biotechnology have been criticized because they have conferred direct benefits to producers, not consumers. That, in turn, has slowed public acceptance of this technology, especially in Europe.

Biotechnology offers the promise of an impressive array of new and useful products that will improve crop yield and quality, provide better nutrition, deliver needed vaccines and medicines, and create new markets for renewable non-food products while using fewer resources, lowering costs, and reducing the environmental footprint of farming. And at a time when many are worried about the fate of the family farm, biotechnology can provide an array specialty products—such as "designer" foods, "pharmafoods," biodegradable plastics, *etc.*—ideal for small-scale agriculture.

But the potential impact of agricultural biotechnology goes far beyond designer crops and products. In meeting the challenge of feeding a rapidly-growing world population, this technology will be seen increasingly as a necessity, not a luxury.

The scope of this challenge is vast. Today, almost 1 billion people live in abject poverty and suffer chronic hunger, about 70 percent of which are farmers (Persley and Doyle, 1999). Future population growth promises to place further demands on food production. It is projected that between 1995 and 2020, approximately 73 million people will be added to the earth's population each year, increasing the world's population by 32 percent to 7.5 billion; 97.5 percent of this growth will take place in the developing world (Pinstrup-Anderson *et al.* 1999).

Over this period, the developing countries will provide the largest increase in demand for food, accounting for about 85 percent of increased global demand for cereals and meat. However, because of environmental concerns and the availability of arable land, it is estimated that the amount of land used for farming can only increase by approximately 7 percent. As a result, the increased demand for foodstuffs will have to be met through greater production. As the rapid growth in yields experienced during the Green Revolution begins to slow, new ways to increase yields will have to be developed (Pinstrup-Anderson *et al.* 1999). Agricultural biotechnology can play a major role in helping developing countries become self-sufficient in food production.

Improving Environmental Stress Tolerance

Combined with a greater understanding of plant genomics, biotechnology can expand the environmental range in which plants can be grown and increase agricultural production in regions of the world with low agricultural output and high rates of malnutrition. Crops that can withstand drought conditions, high salinity, or toxic metals, for example, could enable populations living in currently nonarable regions to farm their land, reducing the pressure on other regions of the world, such as rainforests, that are currently being converted to farmland.

Approximately one-third of the world's irrigated land, including large areas of the Indian-subcontinent, is unsuitable for growing crops due to salt contamination. Researchers have already genetically engineered salt-tolerant *Arabidopsis* and theorize that it should be possible to engineer a whole spectrum of salt-tolerant plants. This would allow farmers to irrigate crops with salt water or water of marginal quality (Frommer *et al.*, 1999).

Other forms of environmental stresses, such as extremes in temperature and drought, have a major impact on crop production. It has been estimated that in the U.S., the average annual yield of the major row crops is only 20 percent of their genetic potential, with most of the "missing" 80 percent being lost due to environmental stresses (Boyer, 1982). In addition, environmental stresses greatly limit the locations where crops can be grown. For instance, due to freezing temperatures, winter canola cannot be grown throughout the northern U.S. or most of Canada. Sudden or unexpected changes in weather conditions can have dramatic effects as well; in California, for example, the citrus industry experienced some $600 million in losses during a spell of freezing temperatures in the winter of 1999 (Thomashow, 1999).

Many traditional plant breeding programs have included efforts to increase environmental stress tolerance. However, these efforts have met with little success because of the physiological and genetic complexities involved in enhancing stress tolerance. The most freeze-tolerant wheat varieties available today, for instance, are only marginally better than those developed in the early part of the 20th century.

In one example of the gains that can be realized by agricultural biotechnology, recent research on environmental stress tolerance has led to the identification of "master switch" genes that control freezing tolerance. As these genes also affect tolerance to drought and high-salinity stress, plants incorporating these master switch genes are currently being developed and tested in a wide range of crop and horticultural species (Thomashow, 1999).

Contamination of soil by toxic metals is another serious problem with which farmers have to cope. Aluminum, for example, is a problem in acid soils in many parts of the Southeastern United States, Central and South America, North Africa, and parts of India and China. Recent research has identified metal-resistance genes in *Arabidopsis*, wheat, and yeast that could be inserted into plants to enable them to grow in soil containing these metals in otherwise-toxic amounts. Taking this technology one step further, researchers are attempting to develop plants that can be used as a cost-effective way to perform environmental cleanup of soils contaminated with metals such as mercury, copper, or cadmium (Moffat, 1999a).

The ability to grow crops in regions of the globe that are presently nonarable, or only marginally so, will greatly reduce the strain on available land, enable those who currently struggle to gain subsistence from the land to feed themselves, and reduce the costs of environmental remediation.

Improving Nutrition

One of the most promising payoffs of agricultural biotechnology is the production of foods with enhanced nutrition. From mitigating the horrific human costs of starvation and malnutrition in

the developing world to reducing disease through dietary improvement, biotech foods have the potential to benefit virtually everyone, no matter where on the planet they reside. These foods will take many forms—plants with higher levels of certain essential amino acids or vitamins, reduced fat levels, increased fiber content, better quality oils, and even anti-cancer properties. The following is a short list of biotech food products that are already on the market or in development:

- Potatoes that contain less starch and therefore absorb less fat during frying;
- Corn and sweet potatoes that contain higher levels of important amino acids, such as lysine;
- Soybeans that contain higher levels of amino acids, such as lysine and methionine, for improved animal nutrition;
- High-sucrose soybeans that taste better and have greater digestibility; and
- New varieties of canola bred for superior oil qualities (ERS, 1999a).

Foods that contain higher levels of beta-carotene or other anti-cancer components are possible and could greatly improve nutritional intake. Advanced understanding of how natural plant substances, known as phytochemicals, confer protection against cancer and other diseases is being used to enhance the level of these substances in the food supply. As Dr. Ryals said, "[W]e can envision a future where...you go to a restaurant and you eat a spaghetti dinner, the spaghetti will be enhanced, possibly [with] a compound that will lower your risk of colon cancer if you eat it once a week. And the sauce that you eat will have antioxidants at a high enough level that it will have some potential benefit...the possibility of this technology is only limited by one's imagination."

Biotechnology will be an critical element in the fight against malnutrition in the developing world. The United Nations Children's Fund estimates that over 200 million children around the world suffer from severe malnutrition, and each year, malnutrition causes the death of nearly 12 million children under the age of five (UNICEF, 1998).

Deficiencies of vitamin A and iron are very serious health issues in many regions of the developing world where rice is a dietary staple. According to the World Health Organization, vitamin A deficiency, which makes individuals vulnerable to infections and blindness, affects approximately a quarter of a billion children. In some regions of the globe, one out of four child deaths is related to vitamin A deficiency. Iron deficiency affects an estimated 3.7 billion people, especially women and children, leaving them weakened by anemia (Gura, 1999).

Recent research conducted jointly by the Swiss Federal Institute of Technology and the University of Frieberg has the potential to address this particular problem. Researchers at these two institutions have used biotechnology to incorporate a total of seven genes from other plants, bacteria, and fungi into rice to produce a new rice strain—Golden Rice—that contains both beta-carotene (the precursor to vitamin A) and iron.

With the assistance of the International Rice Research Institute, this newly-produced rice variety will be cross-bred with commercial strains, field tested, and eventually made available to farmers in all parts of the developing world. Commenting on these developments in the context of the

concerns about agricultural biotechnology raised by activists in the developed world, the journal *Nature* recently editorialized that "such gains could become casualties of the battle being waged over GM crops. If they do, it would be the loss of a golden opportunity to actually help the several billion people in the world whose food doesn't arrive in packaging requiring labeling, if it arrives at all" (*Nature Biotechnology,* 1999).

The Subcommittee also heard about research aimed at improving the protein content of food staples. In many cases, foods such as corn, rice, and other cereal grains are not nutritionally complete because they do not contain all of the essential amino acids needed to build muscle. Diets dependent on these nutritionally-incomplete foods can lead to malnutrition, causing developmental disorders and even death. Because cereal grains comprise as much as 70 percent of the dietary protein for humans in the developing world, 195 million children worldwide are undernourished for protein and suffer stunted growth, weakened resistance to infection, and impaired intellectual development (Larkins, 1999).

Efforts to improve protein content through traditional breeding have been only modestly successful. "Plant breeders throughout the world have worked for more than 30 years to improve the protein quality of maize and other cereals," Dr. Larkins testified. In contrast, he added, "[U]sing molecular genetic and genomic approaches, we were able to unravel the complex problem of the inheritance of lysine-rich proteins in corn. Furthermore, it appears our findings are applicable to other types of cereal grains, including sorghum and wheat, and thus it may be possible to generally improve the protein quality [of] cereals through this strategy" (Larkins, 1999).

Preventing and Curing Disease

Plants have been used for medicinal purposes for thousands of years, if not always to great effect. Medieval "herbals," for example, were medicobotanical compendiums of flora that featured often fanciful accounts of the medicinal value of selected plants. More recently, taxol, a leading anti-cancer drug, was developed from the bark of the Pacific yew tree.

The merging of medical and agricultural biotechnology has opened up new ways to develop plant varieties with medicinal characteristics, including foods that contain pharmaceuticals—"pharmafoods." Dr. Ryals's testimony pointed to the tremendous possibilities for pharmafoods. "[C]onsider that over 50% of all marketed drugs are derived from fungi, bacteria and plants," he said, "With genetic engineering and the rapid discovery pace of genomics, there is no reason why we could not provide these benefits through enhanced diet."

The development of these new varieties will be especially important for populations where access to health care is limited. Vaccination programs remain a problem in many parts of the world, particularly in developing nations, where they are needed most. This is due in large part to a lack of equipment needed to make, store, and deliver vaccines and cultural differences that impede acceptance of injection-based immunization. Given these hurdles, researchers have begun to examine the idea of developing foods enhanced with vaccines that could immunize against disease. Benefits include fewer problems with vaccine storage, more economical production, and avoidance of technical and cultural problems (Thomashow, 1999).

Such considerations have led a number of investigators to pursue the development of edible plant vaccines that could provide more convenient, less costly immunizations. Dr. Arntzen reported that at least 40 new vaccines developed using biotechnology are under evaluation. His research focuses on developing plants capable of delivering vaccines that would protect individuals from the enteric diseases cholera and diarrhea, leading causes of infant deaths in the developing world. While preliminary, these encouraging results suggest that plant-based vaccines may one day provide new strategies for vaccinating humans, farm animals, and pets from these deadly diseases (Arntzen, 1999).

Some plants also may be converted into "factories" designed to produce medicines quickly and cheaply. Scientists are looking at alfalfa, for example, to see if it can be modified to produce interferon-beta, a potentially effective treatment for a form of pneumonia. Other efforts at "molecular farming" also are underway using a variety of plants to produce an array of useful medical products.

Agricultural biotechnology has the potential to provide medicines and edible vaccines to immunize individuals against a wide variety of infectious diseases. These developments will have far-reaching implications for improving human health worldwide, potentially saving millions of lives in the poorest areas of the world.

Providing Renewable Resources

Genetic engineering makes it possible to increase dramatically the use of plants to produce "industrial feedstocks," such as specialty oils for lubricants, precursors of plastics, and valuable health-related biomolecules. New types of fibers and trees enhanced to provide better, faster wood and paper production also are under consideration or development. In all of these examples, biotech plants can provide a renewable alternative to nonrenewable resources.

One example of a crop that could have significant ramifications for long-term environmental protection is genetically engineered cotton with special colors. Such cotton is already available on a niche market basis and may eventually reduce the need for harsh chemical dyes (Dunahay, 1999).

From grain, high-performance industrial lubricants can be generated using biotechnology. An example is found in the work of Anthony Sinskey and his colleges at the Massachusetts Institute of Technology. In June 1999, these researchers launched a multimillion-dollar project to engineer the oil palm to produce everything from improved oils to, conceivably, biodegradable plastics (Moffat, 1999b).

These developments will not only directly benefit the consumer, they also will open up new markets for American farm products and afford farmers greater opportunities in choosing what crops to grow.

Finding: There is no evidence that transferring genes from unrelated organisms to plants poses unique risks. The risks associated with plant varieties developed using agricultural biotechnology are the same as those for similar varieties developed using classical breeding methods. As the new methods are more precise and allow for better characterization of the changes being made, plant developers and food producers are in better position assess safety than when using classical breeding methods.

Central to the debate over agricultural biotechnology is the proposition that new rDNA techniques are inherently different than traditional breeding methods—that the products of these techniques are not "natural," and thus entail greater and often unpredictable risk. In its essentials, this is the message the pejorative "Frankenfoods" is supposed to convey about biotech food products.

Almost all commercially-important crop plants being grown today, including those used in organic farming, have been developed through human intervention and are, in the strictest sense, unnatural. The primary purpose of plant breeding is to create domesticated plants with desirable qualities suited to a managed agricultural environment. As a result, most food crops now in use have been genetically manipulated to such an extent that they bear little resemblance to their wild ancestors.

The ability to move beyond the limits of traditional breeding accounts for much of the appeal of biotechnology to plant breeders. However, it is this ability that is the main concern of many who argue that the new biotech plant varieties, especially those developed using genes from unrelated organisms, entail greater risk than their traditionally-bred counterparts.

The testimony of Mr. Silbergeld is representative of these concerns: "It may be true," he said, "that many applications of this technology are no different than what Luther Burbank did in his time. But Mr. Chairman, you can't cross a fish with a tomato. Fish and tomatoes don't mate. And when, as has already happened, a fish gene is put into a tomato, there should be far different requirements for testing than there is when you are crossing a squash with a tomato or a tomato with a tomato. And so our concern is that things can in fact be done and have been done that can't be done with traditional cross-hybridization" (Silbergeld, 1999).

This argument, however, neglects the salient fact that fish, squash, and tomato genes are not unique to themselves, but are likely to be found in a wide variety of plants and animals. As Dr. Cook explained to the Subcommittee, "One of the great marvels of life discovered mainly during the current era of genomics research is that different life forms already share a remarkably high percentage of the same genes. Even plants and humans have many genes in common naturally. Every biology student learns early that a given gene produces the same protein no matter where in the hierarchy of life forms it may reside. Different life forms are due not only to their gene makeup, but also how all the genes are arranged and coordinately played out. For this and many other reasons, science names genes according to their function or protein they produce and not according to whether they were found in a fish, chicken, or wheat plant."

There are many examples. The genetic material that encodes for the production of the enzyme lysozyme, for instance, is present in both the human and rice genomes.[32] In a recent study published in *Science*, researchers reported that the genome for the fruit fly (*Drosophila melanogaster*) shares 177 of 289 human genes known to cause disease (Rubin, *et al.*, 2000). A more dramatic illustration is the pathogenic bacterium *Escherichia coli*, which shares part of its nucleic acid sequence with plants, amphibians, birds, mammals, and humans (Miller, 1999).

An appreciation of the conservation of genetic material across the plant, animal, and microbial kingdoms is critically important to an understanding of biotechnology and helps explain why the source of the transferred gene—whether from a rat or a pig or a jellyfish—is largely irrelevant in assessing the risk of the new plant variety produced using rDNA techniques.[33] Rather, scientists focus on the function of the gene, the properties of the plant into which it is introduced, and the environment in which the plant will be grown.

Safety questions related to agricultural biotechnology have been examined in great detail by a number of scientific organizations since the mid-1970s, and they have concluded uniformly that bioengineered crops pose no special hazards. In 1987, the National Academy of Sciences determined that "There is no evidence that unique hazards exist either in the use of r-DNA techniques or in the transfer of genes between unrelated organisms," and that "The risks associated with the introduction of r-DNA organisms are the same in kind as those associated with the introduction in the environment of unmodified organisms and organisms modified by other genetic techniques" (NAS, 1987).

These basic principles have been reaffirmed in reports by many other organizations, including the National Research Council (NRC, 1989),[34] OSTP (OSTP, 1992), the Organization for Economic Cooperation and Development (OECD, 1993b), 11 professional scientific societies (IFT *et al.*, 1996), and the Council on Agricultural Science and Technology (CAST, 1998).[35] Dr. Cook informed the Subcommittee that all the field trials conducted and scientific evidence produced since the 1987 NAS report have supported these findings.[36]

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[32] It is estimated that one fourth of the genes in plants are in humans (Cook, 1999).

[33] A good example of this is Golden Rice, which was developed using genetic material from the daffodil, considered a poisonous garden plant.

[34] "[N]o conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular methods that modify DNA and transfer genes. . . Crops modified by molecular and cellular methods pose risks no different from those modified by classical genetic methods for similar traits" (NRC, 1989).

[35] This consortium—comprising the Institute of Food Technologists, American Institute of Biological Science, American Phytopathological Society, American Society for Horticulture Science, American Society for Microbiology, American Society of Agronomy, American Society of Plant Physiologists, Crop Science Society of America, Entomological Society of America, Institute of Foods Technologists, Society of Nematologists, and Weed Society of America—wrote: "The level of risk of a plant variety is not determined by novelty or lack of familiarity, the source of the gene or genes that produce a pest-defense substance or initiate a pest-defense reaction, nor the method by which a gene for pest defense is transferred into the variety" (IFT *et al.*, 1996).

[36] A report by the United Kingdom's House of Lords Select Committee on the European Communities (SCEC) also found agreement in the scientific community on this issue. "In much of the evidence we received," it observes, "witnesses did not distinguish between risks inherent in or particular to the new technology and risks present in standard agricultural practice . . ." (SCEC, 1998).

The testimony also showed that there is broad scientific agreement that rDNA techniques allow greater precision in the introduction of genetic material into a plant compared to hybridization and other conventional breeding methods. Traditional breeding—which Dr. Salyers described as "a genetic crap shoot"—involves the crossing of thousands of genes whose functions are largely unknown. Nevertheless, according to Dr. Huttner, "Each year, thousands of new varieties of fruits, vegetables, and grains are introduced into the food supply. The vast majority include genetic and phenotypic changes that are completely uncharacterized at the chemical or physiological level."

It is worthwhile noting that no product of conventional plant breeding—particularly those involving wide-hybrid crossing, used extensively in crop improvement for many years—could meet the data requirements imposed on biotechnology products by U.S. regulatory agencies. Yet, these foods are widely and properly regarded as safe and beneficial by plant developers, regulators, and consumers.[37]

It is against this background that agricultural biotechnology should be judged. Biotechnology provides plant breeders with ways to insert individual genes into a plant to confer a desired trait without inadvertently introducing an undesirable one. It also enables the complete characterization of the genetics, biochemistry, and mode of action of the genes and the traits they encode. This makes the traits added using rDNA methods much more predictable. "As the molecular methods are more specific," NRC said in its 1989 report, "users of these methods will be more certain about the traits they introduce into the plants."[38] Further, it should be kept in mind that the traits introduced by biotechnology are conferred to commonly-used varieties about which we have a wealth of knowledge.

Since much more is known about the traits introduced using these methods, scientists are able to answer questions about safety that could not be answered for products of conventional breeding. These advantages were explained by Dr. Cook, who said, "Because we know both the genes and their proteins when making transfers by gene-splicing techniques, it also becomes possible to know which proteins are actual or potential toxins before they become part of our food supply. Having this kind of information is much more difficult if not impossible with traditionally bred crops where the genes may be known but the protein products of the genes are only rarely known."

This is not to imply that crops developed using traditional methods are unsafe—centuries of experience with them demonstrates otherwise. Rather, it is to suggest that, as Dr. Cook remarked, "Since traditionally bred crops are accepted as the standard of safety, then crops developed by genetic engineering are at least as safe and are probably safer because of the

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[37] There have been exceptions. For example, the Lenape potato was withdrawn from the U.S. market in the 1960s when it was found to contain dangerously high levels of solanidine glycoside toxins, and a new variety of celery was discontinued in the 1980s because it contained high levels of psoralens, which caused farm workers to develop skin rashes. Both varieties were produced through conventional breeding, but such cases are rare. Given the rigorous scientific and testing protocols in place for biotech crops today, there is no chance that similar products developed using recombinant DNA techniques would pass muster with plant developers or regulatory agencies.

[38] Eleven professional scientific societies reached a similar conclusion: "The more information available about parents and genes transferred to produce a new variety, the more predictable the end-use quality characteristics of that variety" (IFT *et al.*, 1996).

greater precision of the genetic modifications and knowledge of the protein products and their function."[39]

Much of the criticism of agricultural biotechnology focuses on perceived risks. In his testimony before the Subcommittee, for example, Mr. Silbergeld said, "*Consumer Reports* stated quite clearly: there is no evidence that the genetically engineered foods now on the market present safety problems. At the same time, neither can it be said that they have been proven 'safe'. . . [M]any growers and food producer industries characterize these foods as 'safe' because there is no evidence of harm to consumers. However, the 'safe-unsafe' dichotomy may be false. Between these two categories lies a chasm of uncertainty due to lack of knowledge and experience." This concern has been formalized in the "precautionary principle," which calls for regulatory intervention by governments even in the absence of scientific evidence of risk.

The specific areas of concern identified by Mr. Silbergeld, Dr. Goldburg, and others—such as outcrossing, the development of pesticide-resistant insects, allergenicity, toxicity, and antibiotic resistance—will be addressed in detail later in the report. But as a general matter, hypothetical concerns are virtually impossible to dispel. Dr. Beachy put it this way in testimony he submitted to the Subcommittee: "Some of the concerns that are raised lie in the category of perceived vs. actual risk, and we find it difficult, if not impossible, to formulate experiments that address the extremely improbable" (Beachy, 1999).

It is highly questionable, therefore, that raising the regulatory bar and requiring lengthy examinations of improbable risks would advance either public health or environmental protection. A more scientifically-defensible approach is that suggested in a report by 11 professional scientific societies: "Reasonable and continued assurance of safety of each new variety to people and the environment does not require addressing every question that might be asked or every hypothetical concern that might be raised about that variety. The focus must be on high-probability risk rather than hypothetical or unrecognizable risk" (IFT *et al.,* 1996).[40] Adopting a risk-based regulatory approach will ensure that real risks are identified and assessed before a crop or food is released into the environment or the market.

The research scientists who appeared before the Subcommittee made a compelling case that the new varieties developed using agricultural biotechnology are safe. The weight of their testimony over three hearings leads to the conclusion that there is nothing to substantiate scientifically the view that the products of agricultural biotechnology are inherently different or more risky than similar products of conventional breeding because of the method by which they are produced. Dr. Huttner's testimony provides a fitting summary: "The new biotech is actually part of a continuum of breeding technologies that have steadily improved plant and animal breeding and

[39] The same conclusion was reached in a report on agricultural biotechnology published by 11 scientific societies. They said, "[T]he new tools of recombinant DNA technology as an aid to plant variety development are more likely to increase the *safety* rather than the *risk* of new varieties of crop plants to people and the environment" [emphasis in original] (IFT *et al.,* 1996).

[40] This view also was endorsed by the independent research scientists appearing before the Subcommittee.

that provide a centuries-long context for assessing the safety and risk of genetically enhanced plants, animals, and microorganisms."[41]

OUTCROSSING

Finding: The risks that new plant varieties developed using agricultural biotechnology will become weedy or outcross are the same as those for similar varieties developed using classical breeding methods and for introduced species.

Concerns have been expressed that bioengineered crops could develop into weeds or that the genetic innovations produced through agricultural biotechnology could spread to the gene pool of other plants, creating "superweeds" or "genetic pollution." Often, the concern is expressed in a way that links the environmental release of biotech crops with nonindigenous pest species, such as the kudzu vine (*Pueraria lobata*), a nonindigenous plant pest that has been difficult to control since it was introduced in the southeastern United States in the late 19th century.[42]

Extensive field trials overseen by USDA and scientific assessments by major scientific organizations demonstrate that the environmental risk of biotech crops is no different from the environmental risk associated with similar crops bred using conventional means. Because the genetic manipulations being performed today are on crop varieties that already are being grown commercially, we have a broad base of knowledge from which to assess these risks. Standard practices in crop development, field testing, and management will ensure the environmental safety of these crops.

Since the time of Luther Burbank, U.S. plant breeders and agronomists have accumulated a vast storehouse of knowledge and experience on the introduction of genetically-modified plants into the environment and their management. Of the approximately 250 crops plants currently grown in the United States, the large majority are not native species. The early colonists were the first to import plants into North America, and more recently plant breeders and other scientists have imported plants through plant introduction centers maintained by USDA. Nearly all of the plants introduced into the U.S. have undergone extensive selection and breeding to improve their characteristics, adapt them to prevailing environmental conditions, confer resistance to domestic pests, and make them acceptable to consumers (IFT *et al.*, 1996; NRC, 1989).

The risk of a domesticated crop plant accidentally reverting to a weedy condition was described by NAS as "negligible" (NAS, 1987). This is particularly true for crops that have undergone long-term breeding, during which the weedy characters of the wild plant have been removed deliberately from the hybrid.[43] The traits normally associated with domestication make crop plants reliant on a managed agricultural environment, and thus less capable of competing and surviving in the wild and becoming an invasive weed.[44] The addition of herbicide tolerance, pest

[41] Goodman *et al.* (1987) made a similar point: "[I]n plants, and particularly in crop improvement over the last century, interspecific and even intergeneric gene transfer is not new. Gene transfer by recombinant DNA is just the latest in a long history of increasingly more powerful methods available for crop improvement."
[42] For an example, see: Yoon, 1999.
[43] Weedy characteristics can include seed shattering, efficient seed dispersal, long-term seed viability, and thorns, among others.
[44] Examples of crops plants that are minor weeds include sunflower, oilseed rape, and cereal rye.

resistance, and other traits important to improve cultivation have not been shown to confer weediness to domesticated crop plants (NRC, 1989; IFT *et al.*, 1996).[45]

Dr. Cook made this point in his testimony. "I am not aware of a crop plant having become an invasive weed because of plant breeding," he said. "In fact, just the opposite occurs: through plant breeding and selection, wild plants with their tendency to be weeds are made into high-yielding crop plants increasingly more dependent for their survival on human nurturing. There is no evidence after some 20 years of experience with gene splicing to suggest that these trends will somehow reverse towards more wild as we move toward greater use of this new technology."

Moreover, the notional thread between nonindigenous plant pests, such as kudzu, and transgenic crop plants is slender at best. "[Kudzu] illustrates the public's worst perceptions of errant organisms and simultaneously exemplifies an exotic organism that is not analogous to any hypothetical genetically modified organism" (NRC, 1989). Kudzu is a pest not because of any genetic changes made to it through breeding; it is a pest because it was introduced into a wild environment for which it is particularly well-adapted and in which no natural enemies existed. Crops plants modified by means of recombinant DNA techniques, however, are reintroduced "into the same or a similar environment from which they were taken, so they are not analogous to the introduction of nonnative species" (NAS, 1987).

In fact, under today's rigorous regulatory system, there is no way that kudzu would be approved for import or release into the United States. If anything, our experience with kudzu and other nonindigenous pests demonstrates that the introduction—accidental or otherwise—of wild non-indigenous species is a more recognizable and sizeable risk than that posed by the improvement of highly-domesticated crops using biotechnology.[46]

Another concern that has been raised is that herbicide-tolerant or pest-resistant plants could transfer their genetic advantage to nearby weeds, creating superweeds. Gene transfer through outcrossing is a natural process between related plants, but is extremely rare when species are not related. As most crop species in the United States originated elsewhere, there are few wild relatives available for outcrossing, and thus gene flow is a not a significant environmental risk.[47]

In the relatively few cases in which a cross-hybridizing wild relative is present—such as squash and canola—many conditions must be met for gene transfer to occur: the wild relative must be in the range of the crop pollen; the wild relative must flower at the time the crop pollen is available; fertilization must occur in the wild relative and viable seeds must be produced; the seeds must survive and germinate; and the progeny of the hybrid seeds must be fertile or survive vegetatively. If any one of these conditions is not met, the transfer will not be successful (OECD, 1993b).

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[45] In fact, it would be extremely difficult to alter intentionally a domesticated crop plant so that it became a weed because of the complex gene interactions required for such a transformation.

[46] For example, in a recent review of the Nation's biological resources, the United States Geological Survey (USGS) stated, "Nonindigenous species are a major threat to endangered and threaten biota" (USGS, 1998).

[47] Concerning herbicide-tolerant weeds, Dr. Cook observed that they are "a common problem for agriculture, not because of gene transfer, but because of selection for natural resistance."

Even when these conditions are met, the chance that the resistance trait will become incorporated in the wild population absent strong selection pressure is very small. IFT *et al.* (1996), for example, noted that, "Progeny that result from outcrossing may be sterile, but, if fertile, will be hybrids with genomes containing not only the new gene but also millions of other genes transferred with the gamete [*i.e.*, pollen] from the crop plant. Whether such hybrids could then survive and establish or create new hybrids within the wild population is possible but highly unlikely."

In the improbable event that a resistance gene from a crop plant became established in a weed population, the fact that a number of other genes from the crop plant also would be part of the weed's genome means that it will behave more like the crop plant, and its impact will be confined primarily to agricultural fields where it can be controlled through standard management practices (NRC, 1989; IFT *et al.*, 1996).[48] Of course, where the potential for environmental damage is significant, both USDA and EPA have the authority to discontinue field trials and suspend further development of the plant.

Dr. Cook attached as part of his testimony an OECD report, cited previously, that addressed these issues in detail. He said, "This report lists the safety issues for crop plants with genes introduced by the new tools of biotechnology and concludes that they are the same issues raised for crop plants introduced into cultivation directly from the wild without genetic modification or modified by gene transfer within the limits of natural hybridization."

In the years in which have been developing plants using of biotechnology, there is no instance of a new plant variety having created an environmental hazard. The protocols for assessing environmental risks of traditionally-bred plants, developed over many years, are sufficient to provide environmental protection for new rDNA varieties. Regulatory determinations should be based on risk factors, such as the characteristics of the plant and the ecology of the environment into which it is to be introduced, not on the method used to produce it.

Pest-Resistant Crops and the Potential for Pesticide-Resistant Insects

Finding: Widespread use of pest-resistant crop varieties developed using agricultural biotechnology is unlikely to accelerate the emergence of pesticide-resistant insect strains and may actually be more effective in preventing their emergence when compared to spray applications of similar pesticides.

Another concern regarding potential harm to the environment through the use of biotech crops involves plants designed to express various forms of toxins from the naturally-occurring soil bacterium *B. thuringiensis* ("Bt" crops). In her testimony, Dr. Goldburg argued that "Unlike traditional Bt sprays, which degrade quickly in the environment, most transgenic Bt crops produce Bt toxins in all their tissue all the time—whether or not the toxins are needed to control economically damaging pest infestations. The upshot is that Bt crops appear to exert strong selection pressure for the evolution of pests resistant to Bt toxins." If pest resistance to Bt were

[48] For a brief discussion Bt corn and its probable negligible impact on native teosinte in Mexico, see: Martínez-Soriano and Leal-Klevezas, 2000.

to become widespread, then the sprayed form of Bt, which is used widely by organic farmers and backyard gardeners to control pests, would be rendered ineffective.

Insects have proven to be remarkably adaptable and capable of becoming resistant to pesticides. "[T]he emergence of biotypes of pests with ability to defeat genes deployed in crops for resistance to them is nature's way of assuring survival of the species," noted Dr. Cook, "This issue is not new to agriculture. Resistance breeding is an ongoing effort for crops just to stay ahead of the ever-evolving populations of pest species."

The goal of farmers and pesticide manufacturers, therefore, is to stay one step ahead of the insects, not to try to find a pesticide that is "resistance-proof." Such a goal may not be attainable. The possibility exists that Bt-resistant insects will arise regardless of whether Bt crops are planted by farmers. Thus, it is impossible to determine if—or even when—Bt resistance will develop in pest populations.

Concerns about the acquisition of resistance are shared by organic and traditional farmers alike, by the companies that manufacture and market Bt sprays and Bt plants, and by regulators. As a result, industry and EPA, working with farmers, have developed insect resistance management (IRM) programs, such as the requirement of farmers to plant refugia of non-Bt crops. Dr. Goldburg argued that "elements of the [IRM] plans are highly controversial among entomologists and others who believe they are inadequate to forestall the evolution of resistant pests."

The rationale for these refugia is that they will allow Bt-susceptible populations of insects to proliferate, which will then be available to mate with insects that might be carriers of a resistance gene. The existence of the susceptible population will make it less likely that two insects, both of which carry a resistance gene, will mate and thereby create offspring that are resistant to Bt by virtue of having received a resistance gene from each parent—*e.g.* is homozygous for the resistance gene.

The success of the refuge-based IRM plan is based on the assumption that resistance to Bt will likely be a recessive trait, not a dominant one. Thus a recent study (Huang *et al.*, 1999) suggesting that a dominant form of resistance to Bt had been found led some to speculate that the refuge strategy was destined to failure. However, as Dr. Shelton and Dr. Richard Roush, another expert in the field, explained in an article in the journal *Nature Biotechnology*, "Several scientists (including us) have expressed concern about the methodology used in the Huang *et al.* Paper, particularly as the authors did not demonstrate that resistance was actually to the same Bt toxin as in the plant, and did not demonstrate that their 'resistant' population could survive on Bt-corn engineered to express the toxin (a footnote implies that the larvae don't)" (Shelton and Roush, 1999). Without this proof, the study shows only that Bt resistance can arise naturally, in a manner that is totally unrelated to the presence of Bt in the plant.

Another study also published recently in *Nature* led some to question the refuge strategy on different grounds (Liu *et al.*, 1999). The authors of this study reported that insects that eat Bt crops develop slower than non-Bt feeders. They suggested that resistance management programs might therefore fail because the insects eating Bt plants would develop more slowly than their

non-Bt eating counterparts, and thus there might not be any non-Bt eaters around with which to mate (a key element of the refuge strategy) by the time they finally develop. But as Dr. Shelton and Dr. Roush point out, insect generations overlap. Thus, even in insect populations never exposed to Bt cotton, many insects will end up mating with insects from a different generation.

Concerns about insect resistance to Bt predate the existence of biotech Bt crops. Insects resistant to the sprayed form of Bt have been found in the past, and there is some evidence that the sprayed form of Bt may be *more* likely to induce resistance than Bt plants (Roush, 1994). "[T]he only problems with resistance to date for Bt," Dr. Shelton observed, "are as a result of the heavy use of Bt sprays against diamondback moth."

In fact, there is ample evidence to suggest that Bt plants may be a potent weapon in the fight against development of Bt resistance among pest populations. The sprayed form of Bt contains a "cocktail" of different compounds made by the *B. thuringiensis* bacteria, many of which are toxic to insects; each different compound is encoded by a different gene. Today's Bt crops express only one of these genes, thereby producing only one of these compounds. If insects were to gain resistance because of exposure to a particular Bt toxin produced in a plant, it is likely that they would be resistant to that particular toxin only and would still be susceptible to other Bt toxins.

This point was summarized by Dr. Milton Gordon, a pioneer in the field of agricultural biotechnology, in a letter to the Subcommittee: "Talking about *Bacillus thuringiensis* toxin as a single compound is very similar to talking about all of the antibiotics that have been discovered and are now being used in humans as a single compound. If the pathogenic bacteria become resistant to one type of antibiotic, it is possible to switch to another type and still get good results. The same is true of Bt" (Gordon, 1999).

While current versions of Bt plants probably are more effective in reducing resistance than sprayed versions of Bt, future varieties of biotech plants may be more effective still. The technology of "gene stacking," which involves putting multiple genes into a single plant variety, could help achieve this. Although current versions of Bt crops produce only a single form of Bt toxin, future plants can be generated that produce two or more forms. To survive, insects would have to be resistant to each form of the toxin. Multiple genes for resistance have been used for decades to control wheat stem rust in North America, with no evidence of super races emerging that cannot be controlled (Roelfs, 1988). The probability that insects with multiple resistance would arise in an insect population is extremely small.

Another advantage offered by Bt crops is that the dosage is both more predictable and constant. To make the refuge strategy viable, the dose must be high enough to ensure that the vast majority of insects that come in contact with the insecticide die. If the dose is too low, resistance is more likely to develop. Transgenic crops may more effective in preventing the onset of resistance because, as Dr. Shelton explained, "one can regulate the dose of Bt more effectively when it is engineered into a plant than when it is sprayed onto the plant...Sprays will create more variable deposits of Bt on the plant and thus insects will be exposed to a wider series of doses of Bt, including low doses."

MONARCH BUTTERFLY

Finding: The threat posed by pest-resistant crop varieties developed using agricultural biotechnology to the Monarch butterfly and other non-target species has been vastly overblown and is probably insignificant.

In a recent research letter to the scientific journal *Nature*, scientists reported evidence that Bt corn pollen could be deadly to Monarch butterfly larvae (Losey *et al.*, 1999).[49] The study created an immediate stir in the media and was touted by many antibiotechnology activists as evidence that the worst fears about the potential environmental impact of agricultural biotechnology had come true. In her testimony before the Subcommittee, Dr. Goldburg of EDF stated, "widespread planting of Bt corn could harm significant numbers of Monarchs."

Since publication of the Losey *et al.* letter in *Nature*, serious questions have been raised about its findings. A number of prominent entomologists and other experts have dismissed the report as preliminary in nature, restricted to a laboratory environment and thus unrepresentative of real-life conditions, and of limited scientific value. It is also worth pointing out that, as Dr. Shelton testified, the Losey *et al.* study was rejected as a research article by peer reviewers at both *Nature* and *Science*, another highly-respected scientific journal, before being published in the letters section of *Nature.*

Among the reasons for the paper's rejection was that its main finding was not at all unexpected: "[T]he Bt/Monarch study has been heavily criticized in the scientific community because every entomologist knows that...if you feed Monarch butterfly larvae Bt toxin, whether it be in corn or whether it be on a spray, that insect will die" (Shelton, 1999).[50] This opinion was echoed by many respected entomologists, such as University of Nebraska professor John Foster, who wrote in a recent article, "there probably was not an entomologist in the world who was not aware that corn pollen containing the Bt gene could harm butterflies—if butterflies ate corn pollen, which they don't" (Foster, 1999).

Nonetheless, Dr. Goldburg maintained in her testimony that "I think the study was a surprise, unfortunately, to the Environmental Protection Agency....EPA had not even considered this risk," a statement repeated in EDF press releases. However, this claim was directly refuted by the EPA's Dr. Anderson, who said in her testimony, "Our scientists knew the Bt protein is toxic to many insect pests, and in this particular order, the *Lepidoptera.*"[51]

Clearly, scientists were well aware of the potential toxicity of Bt corn pollen to species such as the Monarch butterfly, and were not surprised by the results reported in the *Nature* correspondence. Many have been highly critical of activists and the media, who have portrayed

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[49] In this laboratory-based study, scientists fed Monarch butterfly larvae milkweed leaves (the Monarch's normal food) that had been coated with Bt corn pollen. These larvae were compared to larvae that were fed milkweed coated with non-Bt corn pollen. The comparison revealed higher rates of death or growth defects in the group that was forced to eat Bt corn pollen.

[50] That the various proteins produced by the *B. thuringiensis* are species-specific has been known for some time. The proteins encoded by the *cryI* and *cryII* genes are toxic to insects in the order *Lepidoptera*, of which the Monarch is a member.

[51] This order includes moths and butterflies.

the study as evidence of a real threat to the Monarch butterfly. But in the scientific community, the Losey *et al.* letter was taken for what it was; a preliminary laboratory study that offered little new information and was likely to have little relevance to wild Monarch populations in the field. Even the letter's lead author cautioned that "it would be inappropriate to draw any conclusions about the risk to Monarch populations in the field" (Fumento, 1999).

Since this letter was published, its results have been criticized by many in the scientific community (*e.g.*, Shelton and Roush, 1999; Hodgson, 1999). Preliminary data from other researchers performing field studies show that the concentration of pollen on the milkweed leaves in the Losey *et al.* laboratory study was greater than could be expected in the field (Hansen and Obrycki, 1999). The Monarch's migratory pattern does not bring it in contact with corn during the short time it sheds pollen. Monarchs also prefer to lay their eggs on milkweed plants in open meadows, prairies, and roadsides, not in or around cornfields, as even the *Nature* letter's authors recognized.[52] And as EDF's own literature states, it is widely recognized that "most corn pollen settles out within a few dozen feet of the corn plant" (EDF, 1999), a finding supported by the Hansen and Obrycki field study. Results similar to those recounted above were reported in a conference of scientists held to discuss the issue last November in Chicago (Kendall, 1999).

Taken together, the evidence cited above suggests that the threat of Bt corn to wild populations of Monarch butterflies is vastly overblown. And as for the current state of the Monarch, recent reports indicate that it is flourishing despite widespread use of Bt corn in the Nation's Corn Belt. Jeffery Glassberg, President of the North American Butterfly Association, has added some needed perspective to this controversy. "I think there are a lot more dire threats than that [Bt corn] to Monarchs," he said. "In the Midwest, mowing roadsides and using herbicides is probably much more devastating, actually" (Branom, 1999).

Finally, it should be recognized that any potential effects on non-target species must be compared to other techniques used to mitigate the effects of pests. In the past, pest control has been effected primarily through the use of sprayed insecticides, which often kill both the targeted pest as well as beneficial insects, such as ladybeetles or green lacewings. In contrast, Bt crops preserve beneficial insects that prey on harmful insect pests, thus reducing the need for additional insecticide sprays. Another benefit from using Bt plants is that growers can dramatically reduce the handling and exposure of insecticides on the farm.

ALLERGENS AND TOXINS

Finding: The risks of introducing an allergen or toxin into the food supply are the same for plant varieties developed using agricultural biotechnology as those for similar varieties developed using classical breeding methods.

[52] Earlier research shows that Monarchs identify milkweed plants by sight and typically lay their eggs on small plants that are only three to 18 inches tall (Urquhart, 1998). It is likely, therefore, that Monarchs could identify small milkweed plants scattered among tall corn stalks only with great difficulty.

Americans have come to enjoy a food supply that is not only plentiful, but is widely recognized as among the safest in the world. The suggestion that agricultural biotechnology could threaten the safety of the food supply is a potent argument in the debate over modern agriculture.

Allergens

One of the major food safety concerns raised in connection with agricultural biotechnology is the risk of introducing an allergen into an otherwise-safe food. "The dominant food safety risk associated with genetically engineered crops," Dr. Goldburg testified, "is that foods derived from these crops will cause allergic reactions in susceptible individuals. Genes code for proteins, and when genetic engineers add a new gene to a crop plant they are in most cases adding a new protein to foods derived from the crop. Some of these proteins may be allergens, since all known food allergens are proteins."

Allergies are a reaction of the immune system to a particular protein. Proteins consist of long chains of amino acids, the order of which is unique to every different protein. Allergies are triggered when a person's immune system recognizes a particular protein, or even just a piece of that protein. There are many sources of allergenic proteins. These include nuts, milk, eggs, grains, and fruits, among others.

A first and important line of defense in protecting susceptible persons from exposure to food-borne allergens involves proper testing when known allergenic foods are used in the creation of a new food type. Thus, when a food crop that is known to be allergenic is used as the donor of genetic material in the creation of a new plant-based food, a high standard of proof of non-allergenicity in the resulting food is used.

This is a key component of the approach taken by the FDA in determining the safety of new plant-based foods. As outlined in FDA's Statement of Policy, if a company developing a new plant-based food uses genes from a known allergenic source of genetic material for transfer, the company should assume that this genetic material encodes an allergen unless they can conclusively prove otherwise.

An example of just such a transfer occurred in the mid-1990s, when the Pioneer Hi-Bred International undertook a project to increase the protein content of a soybean variety by introducing a gene from a Brazil nut. Testing discovered that the gene taken from the Brazil nut encoded for an allergen (Nordlee, 1996), and the product was never commercialized. "This [was] a perfect example of how the system works," Dr. Cook testified, "It is always cited as how things can go wrong, but it is exactly how good testing in the laboratory can provide for safety."

It also has been suggested that when a gene is transferred from a non-food organism to a food plant, "it may not be known in advance whether humans will develop food allergies to proteins produced by the non-food gene" (Silbergeld, 1999). While it is highly unlikely that a gene transferred from a non-food organism to a food plant might cause allergic reactions, that possibility cannot be ruled out. However, valuable clues exist that can point to potential trouble, and these clues are used by scientists to avoid this situation. For example, there is a correlation between a protein's stability in the human gut and allergenicity, as food allergens tend to be

more stable than non-allergenic proteins (Astwood *et al.*, 1996).[53] In addition, the protein's amino acid sequence can be compared to other known allergens, and if there are similarities, it can be tested to see if it, too, elucidates an allergic response in susceptible individuals.

Although it cannot be determined absolutely that a gene that sits benignly in one organism will not cause an allergic response when put in another organism, it is important to remember that the introduction of new allergens to the food supply can come from any new food—not just those created through biotechnology. For example, when the kiwi fruit was introduced to this country, a small number of individuals experienced allergic reactions to it. As even Dr. Goldburg, who made clear in her testimony that she is critical of FDA's policies regarding testing for allergenicity, had to admit, "there is no clear-cut mechanism" for determining the allergenicity of any new food product, whether imported or produced using classical breeding or biotechnology methods. Clearly, this is an area where more research is needed. Finally, if a company were to insist upon going ahead with bringing the new food containing a known allergenic compound to market, current FDA policy would *require* labeling of the product.

In summary, the risks surrounding the potential allergenicity of foods created using agricultural biotechnology, while not zero, are quite likely *lower* than for other new foods, because there is at least a target of concern—that being the newly introduced protein and any enzymatic byproducts of it. Once again, the evidence suggests that since more is known about the traits being introduced into a food crop when biotechnology is used, scientists can address safety issues with greater confidence.[54]

Toxins

Another area of debate has been over the question of whether genetic transfers using rDNA technology could result in foods with increased toxicity. Dr. Silbergeld, for example, voiced his concern that "Traditional plants may contain constituent chemicals that are toxic at higher levels but not present in the food at sufficient levels to cause harm. For instance, edible potatoes contain alkaloids that, at higher levels, would be toxic. It is of concern that genetic engineering of a potato, or of another plant that presents this problem, could result in a dangerous increase in toxicity."

Many of the issues surrounding the potential of introducing food toxins to newly created plant-based foods are similar to those involving allergenicity. As with allergens, there is an existing body of knowledge regarding potentially toxic compounds in plants, and so introduction of a gene from a plant known to contain such toxins to another plant is approached carefully and with thorough testing.

Many plant species contain naturally occurring toxins. Potatoes can have high levels of solanine, for example, which can make people ill. Many legumes, such as kidney beans, contain high levels of lectins, which if not destroyed by cooking or removed by soaking, can cause severe

[53] The human stomach is replete with proteases, enzymes that break down proteins into short pieces and even individual amino acids.

[54] Biotechnology also is being used to remove or neutralize food allergens, which will expand the choice of foods available for those who suffer from food-related allergies.

gastro-intestinal distress. Another component of legumes, cyanogenic glycosides, can produce cyanide if the food is not prepared properly. The levels of these cyanogenic glycosides are so high in some foods, such as cassava, that death can result from improper preparation. Cruciferous vegetables (*e.g.*, broccoli and cauliflower), squash, cucumbers, chickpeas, spinach, celery, and many other fruits and vegetables also contain chemicals that are toxic to humans. Yet, each of these foods is consumed widely.

As with allergens, FDA's Statement of Policy outlines a prudent scientific approach to minimize the risk of transfer of a toxicant. A company using a food with a known capacity to harbor toxins as either the donor or the recipient of genetic material is required to verify that any resulting plants do not have unacceptable levels of the toxins.

It is also important to place the potential for creating a new plant-based food with unacceptable levels of toxicity in the context of plants created through cross-breeding. Again, examples exist of foods created through conventional methods that contained unacceptable levels of toxins: the Lenape potato variety in the 1960s and a celery variety in the 1980s. As Dr. Salyers said in her testimony, "making targeted, defined changes in the genomes of plants [using biotechnology] should be safer than the process that created the Lenape potato. Cross breeding, especially between distantly related plants, can bring along all sorts of bad traits with the desired ones" (Salyers, 1999).

Biotech plants also are subject to a greater level of scrutiny than traditionally-bred plants, making it virtually impossible for a biotech version of the Lenape potato to make it to market. These differences were noted by FDA's Dr. Maryanski, who explained that "in the case of most conventional varieties of crops, there are relatively few analytical studies that are conducted during development. This is in contrast to what is done with engineered varieties, where there are far more tests being done for nutrients, toxins, vitamins and minerals and so forth." Again, current FDA labeling policies would require that if a company decided to bring to market a food containing potentially dangerous levels of a toxicant (one that could be mitigated or eliminated by proper food preparation techniques, for example) it would have to be labeled to that effect.

Another concern that has been raised suggests that the development process itself could result in toxicity for unexpected reasons. This claim is not based on fact or example; rather, it is in the realm of hypothetical risk. Mr. Silbergeld, for example, stated that, "*Consumer Reports*...knows of no genetically modified food now on the marketplace that presents any known risk to consumers." But because this unlikely situation is *theoretically* possible, developers of new foods who choose to use rDNA techniques must contend with critics who set the impossible task of proving a negative.

These critics claim that the key to assessing the safety of plants created through biotechnology for human consumption is through extensive toxicological studies, where the entire food item is fed to test animals. There has been one attempt to test a genetically-modified food in this way, and the results were of questionable value.

In what has become one of the most controversial evaluations of a biotech food product, Dr. Pusztai and his colleague in Scotland tested potatoes modified using rDNA techniques by

feeding them to rats (Ewen and Pusztai, 1999). The potatoes had been modified to produce a lectin, a type of chemical compound known to be toxic. The experimental protocol, which has been highly criticized as improperly controlled and executed,[55] involved the feeding of either the lectin-modified potatoes, unmodified potatoes, and unmodified potatoes "spiked" with lectin[56] to small groups of rats.

The researchers claimed that the rats fed the genetically-modified potatoes showed evidence of physiological damage not seen in the rats in the other two groups. However, in the experiment, the rats were forced essentially onto a starvation diet, as rats neither like potatoes nor can get enough of certain essential nutrients from them. Thus, many of the results the researchers saw were quite possibly artifacts of the dietary conditions imposed on the rats.

Many scientific observers see this paper as seriously flawed, as even the editor of the journal in which the article was published—the *Lancet*—recognized. He wrote in an editorial accompanying the research paper that it had been rejected by half of its peer reviewers and that a sizable number of the author's initial claims were left out of the published version because they were unsupported by the evidence. Deflecting criticism of the decision to publish the article, he said, "This is absolutely not a vindication of Dr. Pusztai's claims."

Besides the obvious scientific shortcomings noted in the experimental design of the study, it provides an example of the inherent problems in toxicological analyses of whole foods. These types of toxicological studies are intrinsically difficult. As reported in one article on the subject (MacKensie, 1999), a Dutch researcher attempted to test a genetically modified tomato on rats by freeze-drying the tomatoes so that each rat could be fed the equivalent of 13 fresh tomatoes a day. The scientist is quoted as saying "toxicologists still said we hadn't fed them enough to get a meaningful result." However, the article also pointed out, if they had been fed any more, they would have been poisoned by normally benign nutrients found in tomatoes, such as potassium.

Unable to point to a single documented instance in which a biotech food presented a health risk, critics have focused their concerns on hypothetical risks. However, there was no scientific evidence presented to the Subcommittee that would suggest that the risks of toxicity that attend foods produced using biotechnology are different either in type or degree from those produced using more traditional methods.

ANTIBIOTIC RESISTANCE

Finding: The risk that a health hazard will be created through the use of antibiotic resistance markers in the development of new plant varieties using agricultural biotechnology is insignificant.

In transferring genes to an organism, antibiotic resistance genes often are used to help researchers trace introduced DNA and determine if the transfer was successful. The antibiotic

[55] Among other things, the sample size (6 mice in each group) has been criticized as being too small to draw scientifically meaningful conclusions.

[56] In this case, the lectin was added *to* the unmodified potatoes, as opposed to being produced *by* the potato, as in the genetically-modified version.

resistance gene's only purpose is to serve as a "marker" for the presence or absence of the gene of interest.[57] For this reason, these genes are often referred to as "marker genes," and their use has raised fears that new antibiotic resistant strains of bacteria will emerge. These issues are raised against a backdrop of increasing medical and public concern about serious pubic health threats arising from antibiotic resistance in disease-causing bacteria.

Some types of bacteria are normal residents of the human body. They are referred to as "normal fauna," and they exist in the human intestinal tract without causing any health risk or discomfort to their host. Many are already resistant to common antibiotics. "Virtually all the scientists I have talked with," Dr. Salyers informed the Subcommittee, "agree that since these [antibiotic resistance] genes are already widespread in intestinal and environmental bacteria, an occasional introduction of these genes into bacteria would have no medical significance."

The possibility that normal intestinal bacteria could acquire antibiotic resistance is of little concern to scientists and medical practitioners. Rather, it is the transfer of antibiotic resistance to pathogenic bacteria—bacteria that by definition do not normally inhabit the human body—that is potentially a serious health concern. The British Medical Association has argued that there should be a ban on the use of antibiotic-resistant marker genes because the risk to human health from antibiotic resistance is one of the major health threats facing the pubic (BMA, 1999).

Molecular biology techniques often involve the transfer of antibiotic resistance genes from one organism to another. The application of biotechnology to agricultural products has been no different, and has resulted in plants that carry within their chromosomes DNA that encodes resistance to an antibiotic. Fruits, vegetables, grains, and other foods derived from these plant products will contain this DNA unless treatment of the plant product results in the destruction or removal of genetic material, as is the case in the processing of grains to become cereal or oil. Humans eat DNA from other organisms every day, and all unprocessed plant or animal food products—fruits, grains, vegetables, meat, poultry, eggs, *etc.*—contain the DNA of that organism.

Theoretically, the possibility that an antibiotic resistance gene could be transferred from the DNA of an ingested plant or plant product to pathogenic bacteria exists, but it is exceedingly unlikely because it demands numerous steps, each of which also is highly unlikely: the antibiotic-resistance DNA would first have to be liberated from the plant cell and remain intact long enough to be absorbed by a bacterium; it would have to be taken up by a bacterium after evading it defenses; it would have to become part of the bacteria's own chromosome through a rarely-occurring "illegitimate recombination" event; it would have to become integrated into the bacterial chromosome in just the right way and in the correct position; and finally, it would have to be transferred from the harmless bacterium into which it has been incorporated to a pathogenic one.

[57] For example, if a plant breeder wants to transfer a gene for Bt toxin into plant cells, the researcher first creates a piece of DNA that contains both the Bt gene as well as a gene that confers resistance to an antibiotic, such as kanamycin. To test that the gene transfer was completed, the plant cells are grown in the presence of kanamycin. Resistance to the antibiotic is an indication that the genes were incorporated successfully into the plant cell.

No one actually has been able to demonstrate that such a transfer of resistance genes has occurred in the human gut (Latta, 1999), but it is this scenario that scientists, including Dr. Salyers, agree could create a very a serious health problem.[58] However, a pool of antibiotic resistant non-pathogenic bacteria exists already, and so the impact that biotech foods could have on antibiotic resistance is likely to be insignificant. "There is some disagreement about what the medical consequences of this would be, but most people feel that since the genes are already so widespread in nature, that there would be no medical consequences at all" (Salyers, 1999).

The focus on unfounded concerns over antibiotic resistance transfer from biotech foods has led public health officials in Europe to make poor decisions with potentially grave consequences. As Dr. Salyers explained, "The EU [European Union], distracted by the debate over marker genes in transgenic corn, approved with virtually no debate the use of avoparcin as a growth promoter in animals. As a result, a very serious form of bacteria resistant to vancomycin (an analog of avoparcin) has been introduced into their food supply. Since colonization of the intestines of humans by these bacteria could possibly lead to their death due to subsequent untreatable post-surgical infection, this is a serious health concern." Thus we are provided with another instance in which a more immediate risk has been ignored while the insignificant risks posed by agricultural biotechnology have been blown out of proportion.

In any event, as scientists find ways to use marker genes that do not involve antibiotic resistance, the point will become moot. As recently reported in *Nature Biotechnology*, researchers already have begun to develop such alternative marker genes (Kunkel *et al.*, 1999). Although this should quell the debate over antibiotic resistance transfer from biotech foods, Dr. Salyers suggested that the ongoing controversy over antibiotic resistance markers "sets yet another precedent for allowing public policy decisions to be driven by bad science."

SUBSTANTIAL EQUIVALENCE

Finding: The concept of "substantial equivalence" in the regulation of foods developed using agricultural biotechnology is scientifically sound and provides a useful historical baseline for judging safety.

The principle of "substantial equivalence" has been adopted by many national and international governmental and scientific organizations as a way to assess the risk of biotech food products. This principle holds that the risks of a new food variety produced using biotechnology are the same as those for an existing variety with essentially the same characteristics. It therefore establishes existing varieties, the vast majority of which have a history of safe use, as the standard for safety.

This concept—though widely accepted by the scientific community as a sound basis for risk-based regulation—is not without its detractors. As Millstone and colleagues have argued, "Showing that a genetically modified food is chemically similar to its natural counterpart is not adequate evidence that it is safe for human consumption" (Millstone, *et al.*, 1999).

[58] Attempts by researchers at the University of Leeds to get various bacteria to take up and activate the *bla* gene, which confers resistance to ampicillan, from maize developed using rDNA technology have been unsuccessful so far (Coghlan, 2000).

Genetic manipulation by any method raises the possibility of inducing one or more unexpected and unrelated changes in a plant. These changes, referred to as pleiotropic events, are not a unique risk factor in biotechnological approaches. These unexpected events could include (1) activation of a normally latent gene or set of genes and (2) disruption and subsequent de-activation of a normally active gene or set of genes, and they could occur with any genetic modification process.

Determining conclusively that genetic modification—whether done through traditional breeding techniques or biotechnology—has not resulted in any unexpected events in the plant is extremely difficult. Even if such tests were practicable, it is questionable whether the differences that emerged would be meaningful or indicative of potential danger, as they could easily lie within the normal—and perfectly safe—ranges of variability brought on by different agronomic conditions.

FDA's policy approach is consistent with the concept of substantial equivalence. In evaluating substantial equivalence, factors such as the concentration and bioavailability of important nutrients for which the plant-based food is consumed are measured. These typically involve biochemical measurements of the levels of protein, carbohydrates, fats, oils, and certain vitamins or other important nutrients.

These standards, and the concept of substantial equivalence itself, are applied only to biotech plants, even though the same potential risks exist for plants created through more traditional means. In comparing these standards for crops created through agricultural biotechnology versus those that are not, Dr. Maryanski said during testimony before the Subcommittee, "in the case of conventional varieties of crops, there are relatively few analytical studies that are conducted during development. This is in contrast to what is done with engineered varieties, where there are far more tests being done for nutrients, toxins, vitamins and minerals and so forth, as a way of providing that additional assurance that the important components of the plant are at the levels that are expected."

Critics of substantial equivalence contend that toxicological tests on the whole food, not just the novel components of the food, must be done on products of agricultural biotechnology to draw conclusions about their safety. Toxicological studies involve clinical analyses, where a whole food is consumed by a test animal to determine if unexpected events show up. In short, critics of substantial equivalence contend that "the total food is greater than the sum of its parts," and that whole-food testing is superior to detailed biochemical and immunological analyses or toxicological studies of individual components (Millstone, *et al.*, 1999).

However, the testimony suggests that toxicological tests on whole foods do not provide a sound basis upon which to draw informed conclusions about food safety. "Such testing," said Dr. Taylor, "would be tremendously unfocused, wasteful of laboratory animal resources, and unlikely to detect any harmful substances, even if they were present. The novel proteins and their products in GMO foods are often present at very low levels and their effects, if any, would not be detected by feeding the whole GMO food to lab animals" (Taylor, 1999). To date, there is only one published example of whole-food toxicological testing of a biotech food (Ewen and

Pusztai, 1999), and that, as we have seen, was not regarded highly even by the editors of the journal that published it.

What critics of the concept of substantial equivalence tend to lose sight of—or gloss over entirely—is the fact the same risk factors that they contend are present in foods developed using agricultural biotechnology are every bit as possible for plants created using more conventional means, such as cross breeding. Genetic events that result in the reshuffling of genes, for example, or that could cause a normally inactive gene product or biochemical pathway to become active (or vice versa), also can occur in the course of conventional plant breeding. Thus, even if toxicological testing were feasible and provided useful and meaningful data, proponents of this type of analysis should be demanding with equal fervor that such testing be done for all new varieties of plant-based foods.

The concept of substantial equivalence is widely regarded in the international scientific community as more than adequate to safeguard food quality and wholesomeness. OECD, for example, concluded: "For food and food components from organisms developed by the application of modern biotechnology, the most practical approach to the determination of safety is to consider whether they are *substantially equivalent* to analogous conventional food product(s), if such exist" (OECD, 1993c). It also has been validated by the World Health Organization (WHO), the United Nations Food and Agricultural Organization (FAO), and the International Life Sciences Institute. Further, many governments have adopted this concept as part of their review of food crops created using biotechnology, and it provides the conceptual basis of FDA's 1992 Statement of Policy. "With the global endorsement of the concept of substantial equivalence," Dr. Taylor said, "I think that I am on rather solid ground to advise that this concept should be retained."

Based on the testimony and other material reviewed by the Subcommittee, there is no reason to question the validity of substantial equivalence. Although the focus of this discussion has been food safety, the evidence suggests that this regulatory approach applies equally well when considering environmental safety.

LABELING

Finding: There is no scientific justification for labeling foods based on the method by which they are produced. Labeling of agricultural biotechnology products would confuse, not inform, consumers and send a misleading message on safety.

Whether FDA should mandate labeling of foods produced using agricultural biotechnology is another area of growing controversy. Consumers Union, which was represented at hearings held by the Subcommittee, is one such group calling for labeling of biotech foods, and it has accused FDA of being "a cheerleader for a technology" for not agreeing to implement such a requirement (Silbergeld, 1999). On November 30, 1999, legislation was introduced in the House of Representatives that would require that foods containing genetically engineered material, or produced with a genetically engineered material, be labeled accordingly.

The criticisms of FDA's policy on labeling are unfounded. The FDA now has more than 15 years of experience in evaluating the food-based products of biotechnology and more that 20 years of experience with medical products of biotechnology. The agency's decision not to require labeling is consistent both with the law and with its Statement of Policy. More to the point, consumers have a lifetime of direct personal experience with foods genetically modified through hybridization that are indistinguishable from those produced using biotechnology.

FDA bases labeling decisions on whether there are material differences between the new plant-based food and its traditional counterpart. These material differences include changes in the new plant that are significant enough that the common or usual name of the plant no longer applies, or if a safety or usage issue exists that warrants consumer notification (FDA, 1992).

One such safety issue involves the introduction of allergens from one food source to another. As discussed earlier, FDA has stated that a gene that is introduced into a plant from a source that is a known allergen will be presumed to be allergenic—and thus be labeled as such—unless the company that wishes to bring the new food to market is able to demonstrate otherwise. This is a rigorous standard that places the burden of proof squarely on the company developing a new plant-based food.

Despite this sensible policy, biotechnology's critics continue to argue that foods created using rDNA techniques should bear a label revealing that fact. This view is based in large part on the faulty supposition that the potential for unintended and undetected differences between these foods and those produced through conventional means is cause for a label based solely on the method of production of the plant.

The risks for potentially unintended effects of agricultural biotechnology on the safety of new plant-based foods are conceptually no different than the risks for those plants derived from conventional breeding. As described in FDA's Statement of Policy, "The agency is not aware of any information showing that foods derived by these new methods differ from other food in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding" (FDA, 1992). This view was echoed by the research scientists who testified before the Subcommittee on the subject.

Some activists and consumer groups, however, have suggested that foods created through biotechnology should be labeled in the interests of providing consumers with information. But when given the option, consumers favor all sorts of information that could not possibly fit on a label—everything from information on where and under what environmental and labor regulations it was grown to the pesticides, herbicides, and fertilizers used to protect it and promote its growth. None of this information is required by FFDCA, which focuses on the nutritional and health aspects of food. When asked if he supported labeling of foods produced using biotechnology, Dr. Cook responded by saying, "labeling of foods...just because of the method used to genetically modify the crop...would not provide useful information on safety or nutritional value of the food."

Whether a label provides relevant information to a consumer also depends on how the consumer perceives the label. Dr Salyers, for example, made the following point: "Whether genetically engineered foods should be labeled or not depends on what the label means to the public...In the current atmosphere, where the public has been given erroneous and misleading information about genetically engineered foods, labels would have exactly the opposite effect from the intended effect."

There is a genuine fear that labeling biotech foods based on their method of production would be the equivalent of a "skull and crossbones"—that the very presence of a label would indicate to the average consumer that safety risks exist, when the evidence shows that they do not. Labeling advocates who argue otherwise are being disingenuous. The United Kingdom's new mandatory labeling law, for example, was put forward to enhance consumer choice. Instead, it has prompted British food producers and retailers to remove all rDNA constituents from the products they sell to avoid labeling.

Polls showing public support for labeling of biotech foods also need to be put into perspective. A poll of New Jersey residents, for example, found that only 59 percent of the citizens surveyed approved of the production of plants through traditional hybridization techniques,[59] and 20 percent believe that it is morally wrong to produce plants this way (Hallman and Metcalfe, 1999). Given the apparent lack of knowledge of traditional plant production methods—methods that have been used safely for hundreds of years—labels indicating the method of genetic manipulation clearly would be extremely confusing, and of little relevance, to consumers.

OVERSIGHT

Finding: Federal regulations should focus on the characteristics of the plant, its intended use, and the environment into which it will be introduced, not the method used to produce it. Regulations that capture selectively the products of agricultural biotechnology do not reflect the scientific consensus on risk, are overly burdensome, and stifle scientific research.

The conceptual basis for risk-based oversight polices established in the Statement on Scope is that the risks of organisms produced by biotechnology are the same as those produced by traditional methods, such as hybridization, and that regulations should focus on the characteristics of the plant, not how it was produced. There is a broad scientific consensus in support of this premise.

For example, a 1987 NAS report concluded that, "There is no evidence that a gene will convert a benign organism onto a hazardous one simply because the gene came from an unrelated species," and that environmental risk assessment of genetically-engineered organisms "should be based on the nature of the organism and the environment into which it will be introduced, not by the method by which it was modified" (NAS, 1987). These findings were reaffirmed in subsequent reports by NRC (NRC, 1989), OECD (OECD, 1993b), 11 professional scientific societies (IFT *et al.,* 1996), CAST (1998), and the testimony of the research scientists who appeared before the Subcommittee.

[59] Interestingly, the same poll found that 61 percent of respondents approved using biotechnology to produce new varieties of plants.

However, application of these principles across regulatory agencies has been uneven. While FDA has done a reasonably good job of resisting regulations designed to capture products developed using biotechnology, regulations at USDA and proposed regulations at EPA deviate from the risk-based, scientifically-sound regulatory principles set out in the Statement on Scope and in reports by various scientific bodies.

U.S. Department of Agriculture

In 1986, as part of the Coordinated Framework, USDA's APHIS proposed new regulations under the Plant Pest Act and the Plant Quarantine Act restricting the introduction of plants engineered through rDNA techniques that are "plant pests or which there is reason to believe are plant pests" (OSTP, 1996). As the plasmid of *A. tumefaciens* and the regulatory sequence from the cauliflower mosaic virus often are used to introduce and drive the expression of genes, respectively, in bioengineered plants, these regulations ensure that the majority of plants developed using rDNA technology are regulated by the Department.

The DNA molecules used in these transfers are efficient and reliable mechanisms for introducing new traits in plants. They do not cause domesticated crop plants to become plant pests. Nevertheless, USDA regulatory requirements are triggered by the use of these rDNA methods, and thus depart from scientifically-based measures of plant pest risk.

Dr. Huttner argued that USDA's interpretation of the Plant Pest Act "essentially equated a genetically engineered plant as a potential plant pest and created new permit requirements for plant breeding research involving even small scale field trials. The regulation turns on a new definition, 'regulated article,' which determined that the presence of any part of a known plant pest could provide reason to believe a genetically engineered plant could present risk as a plant pest."[60] She added that USDA's policy also could create the odd situation in which "two identical plants that differ only in their method of genetic modification would be treated very differently by the agency: one would be subject to stringent regulation and the other would be completely free of regulation."

It is understandable that USDA initially took a cautious approach when dealing with a new technology. However, as Dr. Huttner noted, many years of successful field tests and other information on biotech plants have demonstrated that these methods of recombining DNA do not turn harmless crop plants into plant pests. An editorial by Dr. Arntzen appearing in *Science* magazine in 1992 drew the same conclusions and called for USDA to change its regulatory policy. "The scientific community acquiesced to these regulations," he wrote, "largely based on uncertainty of public acceptance of biotechnology products and the specter of interference from activists in field-testing research. The successes of field tests conducted to date . . . removes the earlier uncertainty. . . There is an urgent need to revise the USDA/APHIS regulations to focus on the behavior of rDNA-modified plants and not on experimental protocols" (Arntzen, 1992).

[60] Dr. Arntzen made a similar comment in a 1992 *Science* editorial: "The premise [of USDA/APHIS regulations] is that when plants are developed using genetic material from pathogenic sources or when a pathogenic organism is involved in causing the plant transformation, the resultant plant must be subjected to regulatory analysis to assure that it does not pose a risk to other plants" (Arntzen, 1992).

USDA's notification policy has streamlined the process somewhat, but as regulated articles, these plants are still subject to monitoring and reporting requirements, adding substantially to the cost of developing new varieties using existing rDNA techniques. Dr. Huttner estimates that USDA's regulatory policy makes current approaches to rDNA modification 10 to 1,000 times more expensive for plant breeders than conventional approaches.

Proposed Organic Standards. USDA's recently-announced proposal on national standards for organic foods also differentiates between plants developed using rDNA technology and traditional breeding methods. The proposed rules, which reflect intensive lobbying from the organic farming industry, prohibit foods derived from biotech plants from carrying the organic label. This is especially ironic in that genetic manipulation to develop plants with pest resistance has made organic farming possible. There is no scientific justification for excluding plants modified using rDNA techniques from the organic standards if they are grown and processed in accordance with those standards.

Environmental Protection Agency

The scientific community also has voiced its misgivings about EPA's proposed rule on plant pesticides. EPA's proposal would exempt or regulate plant pesticides based on the sexual or taxonomic relationship between the organism from which the gene came and the plant into which it is inserted or the novelty of the trait conferred.

Application of this standard would lead to peculiar effects. If a gene encoding for a substance that enables a plant to resist pests was moved from one tomato variety to another via rDNA techniques, for example, it would be exempt from EPA regulations. But if that same gene came from a species of bacteria, it would be subject to regulation. "These new crop varieties," said Dr. Anderson, "have no long-term established record of safe human consumption. It is incumbent upon the Agency to protect the public from any potential risks stemming from their use by evaluating potential risks, establishing tolerance levels, and registering safe products." Further, she added that EPA's approach would focus only on those plant products "that present novel exposures and more toxic modes of action . . . EPA does believe that pesticidal substances with new exposure to humans or the environment need to be carefully reviewed before being released into commercial agriculture."

By relying on sexual incompatibility or novelty as a regulatory trigger, EPA's proposed rule would place the focus squarely on pest-resistant plants produced using biotechnology. So concerned was the scientific community with this proposal that in 1996, 11 professional scientific societies—representing 80,000 plant, food, and microbiological scientists—took the unusual step of issuing a report on it. They observed that EPA assumes "that traits transferred from outside the normal range of sexual compatibility of the recipient plant will increase the likelihood of novel exposures or hazards to human health or the environment," even if the gene is present in other crop plants (IFT *et al.*, 1996).

In examining EPA's proposed rule, they found that: (1) it is scientifically indefensible to regulate pesticides produced by plants under statutes developed specifically for chemical pesticides

applied externally to plants; (2) all plants are able to prevent, destroy, repel or mitigate most potential pests; (3) while pest resistance can be conferred by specific genes, the ability to resist pests is a characteristic that cannot be separated from the plant itself for regulatory purposes; and (4) the evaluation of the safety of substances in plants should be based on the toxicological and exposure characteristics of the substance and not on whether the substance confers protection against a plant pest.

From this, IFT *et al.* concluded that EPA's proposal is at odds with the principle, put forth by many scientific panels, that the risks of introducing a new variety into the environment are related to the characteristics of the organism and its growing environment, not the source of the genetic material and the process used to transfer it. A panel convened by CAST—whose membership includes over 40 different scientific organizations from the United States and Canada—reviewed the IFT *et al.* report and reached the same conclusion: "[R]egulating the inherited traits of plants for pest resistance because the traits were introduced by genetic engineering and not through conventional breeding is scientifically invalid" (CAST, 1998).

EPA's proposal would erode unnecessarily consumer confidence in agricultural biotechnology by implying that biotech plants contain pesticides, as that term is commonly understood. As both IFT *et al.* and CAST point out, resistance to pests is the rule, not the exception, in plants, and plant breeders have been improving natural defenses using conventional breeding techniques. These pest-resistant varieties have been grown and consumed safely for many years, yet we have very little knowledge of how the resistance is expressed either chemically or physically. This led both groups to conclude that it is scientifically indefensible to regulate pest-resistant biotech plants under rules designed to regulate chemical pesticides applied externally to plants.

Further, there is no scientific reason for EPA to exempt plants developed using rDNA technology if the transferred gene came from a sexually compatible plant. New genetic techniques now allow plant breeders to increase production of naturally-produced pesticidal substances within plants that at low levels are harmless but that at higher levels may pose risks. It bears repeating that the scientific community is in agreement that oversight should focus on the characteristics of the plant, regardless of the source of the transferred genetic material.

Unnecessary Regulation Creates Disincentives

In the nearly two decades in which the United States has dealt with agricultural biotechnology, there has never been a single case in which a crop plant or food developed using rDNA techniques has resulted in damage to the environment or human health.[61] Despite this uninterrupted record of safety, U.S. oversight has been criticized as being too lax.[62] Dr. Cook's

[61] There is a temptation to credit the stringent U.S. regulatory system for this impressive record of safety. The main reason for this success is much simpler—the products of agricultural biotechnology are inherently as safe as the products of classical breeding.

[62] The suspicion with which European critics view U.S. regulatory institutions stems in part from the number of food- and health-related scares that have occurred in Western Europe recently—*e.g.* "mad cow" disease (bovine spongiform encephalopathy) in the United Kingdom, contaminated soft drinks in Belgium, and HIV-tainted blood in France. Surveys show that while American consumers display a high degree of confidence their regulatory agencies

testimony provides an apt response: "[B]etween the extensive performance trials and institutional reviews conducted by the developers of genetically modified crops, typically involving years of field testing, and the regulatory framework in place at the federal and state levels to assure safety of new crops or old crops with new traits, it is hard to imagine what more can be done to assure the safety of genetically modified crops to people and the environment."

Indeed, there needs to be greater recognition that regulations that discriminate against the products of biotechnology, based on their method of production, create disincentives for researchers and plant developers. Dr. Huttner, in particular, voiced her concern that existing regulations at USDA and the proposed regulations at EPA could increase significantly the cost of developing new plant varieties using rDNA technologies. She said, "Because the regulations selectively apply to the use of new biotechnologies, the resulting added costs put biotech businesses at a disadvantage relative to competitors that use conventional, older techniques. The effect on entrepreneurial start-up firms can be particularly serious, affecting even the structure of an emerging industry." IFT *et al.* and CAST also commented on the harmful impact increased regulations can have on small companies and public plant breeding programs developing biotechnology products for niche markets.

Unwarranted regulations also will have an impact on the academic community engaged in biotechnology research. It is already happening in Europe, where researchers reportedly either are leaving the field or are seeking opportunities elsewhere. If the United States is to keep its lead in this area, it is important to maintain a top-notch research capacity. Tangling up researchers in red tape will waste research dollars and stall progress.

Politically-Motivated Opposition

Finding: Much of the opposition to agricultural biotechnology is politically motivated, not scientifically based.

Notwithstanding the scientific consensus that new crop varieties and foods developed using agricultural biotechnology are at least as safe as those developed using conventional breeding, well-funded antibiotechnology activists have been effective in using a patina of science to spread unfounded fears about these products. In the words of Dr. Cook, "What needs to be more widely recognized is that raising doubts about safety is only a route to carrying out a more fundamental social, economic, or political agenda. What better way to generate a ground-swell for labeling or even outright elimination of GMOs from commercial agriculture than to raise doubts in the minds of people about safety, when safety is not really the issue?" (quoted in Huttner, 1999). When Norman Borlaug, the Nobel Prize-winning agronomist, was asked recently to explain the opposition to agricultural biotechnology, he said simply: "It's political. It's not scientific."

For many biotechnology opponents, the political agenda to which Dr. Cook referred seems to be to stymie the biotechnology industry and to replace large-scale agriculture with primarily organic farming to meet the world's food needs. Modern agricultural practices often have been criticized as being unsustainable because of their reliance on inputs of chemicals and water. But as many

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can ensure food safety, European consumers display a high degree of distrust in their regulatory agencies (Gaskell *et al.*, 1999).

witnesses expressed to the Subcommittee, the driving motivation of much of the research in plant genetics is to reduce the environmental impact of farming, ostensibly a goal of many of biotechnology's sternest critics. There is substantial evidence that agricultural biotechnology will provide environmental benefits well beyond decreases in pesticide and herbicide use. For example, new varieties of low-phytate corn for animal feed produce less phosphorous in the waste passed by the animal, thus reducing pollution from animal farms. In addition, higher yields resulting from genetic improvements can reduce the pressure to convert valuable ecosystems, such as rainforests, to agricultural production. These and other significant environmental benefits are neglected deliberately in the international campaigns of activist groups.

The biotechnology industry also has been criticized for being concentrated in the hands of a few large multinational companies based in economically-advanced countries. This concern also is misplaced. Both Dr. Ryals and Dr. Cook pointed out that agricultural biotechnology represents a technological revolution comparable to those that gave birth to the power, transportation, and computer industries, each of which has conferred tremendous benefits to consumers. It is expected that as agricultural biotechnology becomes more industrialized, increasing competition will lead to consolidation within the industry and adoption of the technology by consumers worldwide, similar to what has happened in these other industries. But consolidation will not lead to monopoly, as entrepreneurs will develop niche markets for specialty products, similar to those that have developed in other mature industries.

In an industry changing as rapidly as biotechnology, it is hard to foresee a company or small group of companies gaining domination over global food production. Ironically, increasing the regulatory burdens on agricultural biotechnology, which many biotechnology critics advocate, would succeed only in giving a distinct competitive advantage to large companies able to pay the added costs of regulation. This is hardly the way to promote competition or to foster the spread of this technology to developing countries.

The most potentially damaging claims of activist groups, as Dr. Cook observed, raise doubts about the safety of foods from bioengineered plants, despite overwhelming scientific evidence that these doubts are unfounded. It is interesting to note, therefore, that among agricultural biotechnology's most ardent critics is the organic farming industry. The irony of this was noted by Dr. Salyers, who told the Subcommittee, "There is no question that organic produce is potentially more dangerous than genetically engineered plants. In particular, insect damage creates tissue that is easily invaded and colonized by fungi that produce a variety of mycotoxins, of which ergot and aflatoxin are two examples."[63] In addition to higher levels of certain mycotoxins, data suggest that organic foods also are more likely to contain harmful bacteria, such as *E. coli* (Avery, 1998).[64]

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[63] Other witnesses appearing before the Subcommittee made similar comments. For example, Dr. Ryals said, "'Organically-grown' is not synonymous with safe and it is a mystery to me why anyone thinks that it is."

[64] In an analysis of data from the Centers for Disease Control, Dennis Avery, Director of the Center for Global Food Issues, found that people who eat organic foods are eight times more likely to contract a new strain of *E. coli* bacteria (0157: H7) from food. "Organic and 'natural' food producers supply only about 1 percent of the nation's food," he wrote, "but the Centers for Disease Control have traced approximately 8 percent of the confirmed *E. coli* cases to such foods" (Avery, 1998).

Biotechnology can improve food safety by lowering exposure to harmful substances in foods. Dr. Cook told the Subcommittee of research showing that grain from Bt corn has significantly lower concentrations of fumonosin, a mycotoxin produced by the fungus *Fusarium moniliforme* that has been linked with esophageal cancer. *F. moniliforme* is known to thrive in ears of corn damaged by the corn ear worm. "It would be more difficult to control the corn ear worm with BT sprayed as a biopesticide on the corn, as approved by the organic standards," he said, "since this kind of application would be less likely to control worms that burrow inside the ears and kernels of corn."

Capitalizing on the near-hysteria in Europe about food safety, Europe's political leaders have invoked the "precautionary principle"—which asserts that governments may make political decisions to restrict a product even in the absence of scientific evidence that a risk exists—as cover for protectionist regulatory policies that have shut out American farm products from European markets. Biotech crops also are seen as an economic threat in Europe, where governments encourage low-yield farming techniques. In a free-trade environment, trade decisions should be science-based, as World Trade Organization (WTO) rules stipulate. American researchers and farmers need to know that they will have a market for their products.

What is perhaps of greater concern is the impact European attitudes could have in other agricultural and food markets around the world, particularly in the developing world, where biotechnology can address so many health and environmental problems. A well-reasoned view of needs of the developing world has been provided by Dr. Florence Wambugu, a prominent agricultural researcher in Kenya. She recently wrote, "The needs of Africa and Europe are different. Europe has surplus food and has never experienced hunger, mass starvation and death on the regular scale we sadly witness in Africa. The priority of Africa is to feed her people with safe foods and to sustain agricultural production and the environment...The criticism of agribiotech products in Europe is based on socioeconomic issues and not food safety issues, and no evidence so far justifies the opinion of some in Europe that Africa should be excluded from transgenic crops. Africans can speak for themselves...The African continent, more than any other, urgently needs agricultural biotechnology" (Wambugu, 1999).[65]

In the politically-charged atmosphere created by antibiotechnology activists, scientists like those who appeared before the Subcommittee operate at a distinct disadvantage because of the demands placed on them by the scientific culture, which prizes dispassionate discussion of the evidence and the arguments, not hyperbole and sound bites. Dr. Henry Miller, founding Director of FDA's Office of Biotechnology, recently summed up the situation this way: "We cannot change [the antibiotechnology extremists'] minds by making scientifically reasonable arguments, asserting the primacy of empirical evidence and the scientific method, or invoking the benefits to the public of new products and new choices. They are not engaged in a good-faith effort to advance the public interest" (Miller, 2000).

As if to confirm Dr. Miller's assessment, some extreme antibiotechnology groups have resorted to vandalism and worse. Since Greenpeace activists first destroyed a farm field in Iowa in 1996,

[65] Biotechnology already is having an impact on farming in Africa, where a new variety of sweet potato developed by Monsanto and the Kenya Agricultural Research Institute to resist the feathery mottle virus has been introduced. See: Qaim, 1999.

there have been over 100 reports of property destruction, arson, assaults, and other acts of intimidation against people involved in biotechnology.[66] Recently, Michigan State University's Agriculture Hall, a 91-year old landmark building housing the university's Agricultural Biotechnology Support Project, was severely damaged in a fire for which a radical environmental group, the Earth Liberation Front, claimed "credit." Weeks later, the same group broke into a University of Minnesota lab and uprooted 800 oat plants that were part of a study aimed at improving disease resistance. These criminal acts have put people's lives at risk, disrupted careers and important research, threatened scientists, and violated the accepted norms of debate and decency in a free and democratic society.

The scare stories now being spread about agricultural biotechnology bear no relation to the testimony received by the Subcommittee. The research scientists have exciting stories to tell, but they must be told more forcefully if they are to rise above the strident voices of those whose political agenda, if adopted, would significantly set back scientific progress and limit consumer choice.

[66] In the United Kingdom, Friends of the Earth, an antibiotechnology activist group, mailed letters threatening legal action to scientists working for research centers involved in agricultural biotechnology. The letters said that researchers would be held "personally legally liable" for damage caused by the growing or consumption of genetically modified crops. Representatives of the John Innes Centre, which received such a letter, stated that the campaign was a "crude attempt to harass and intimidate individuals" (Radford, 1999).

RECOMMENDATIONS

An analysis of all the testimony and other material made available to the Subcommittee leads to the following recommendations.

PLANT GENOME RESEARCH

Recommendation: Congress should ensure adequate levels of funding for the National Plant Genome Initiative. Efforts to link basic research in plant genomics with local plant breeding programs at Agricultural Experiment Stations and with Cooperative Extension should be increased.

The United States is the world leader in agricultural biotechnology. However, maintaining preeminence in this field will require a sound research base from which new technologies and products can be developed.

The National Plant Genome Initiative is a well-managed public asset that represents a wise use of taxpayer dollars. Current sequencing efforts on *A. thaliana* have improved immeasurably our understanding of the genomics of a typical flowering plant. The shift in emphasis from gene sequencing to functional genomics is the logical next step that should provide the intellectual basis for new varieties of commercially-important crops and other plants. Further understanding of plant genomics also should provide insights that could be used to inform and streamline the regulatory process.

The testimony is clear that plant genome research already has paid off in significant ways, and further advances have the potential to reap new knowledge and spawn entire new industries. Dr. Ryals, in particular, noted that the foremost rate-limiting step in agricultural biotechnology is gene discovery. Therefore, in making appropriations, Congress should provide sufficient funding to continue this important work.

It also is important that we use productively the research results generated through this program. NSF, USDA, and the other participants in the plant genome program have done a credible job of making the results of the research it funds available to other researchers and the private sector. Partnerships among universities participating in the program, agricultural experiment stations, and private-sector companies also have developed. These should be encouraged further, and more formal structures concentrating research efforts in plant genomics, plant breeding, and agricultural extension should be considered to attract increased private sector participation and get new varieties to the field sooner.

The American taxpayer is making a considerable investment in basic plant genome research. The payoffs from this investment will depend in large part on our ability to capture and apply the social benefits from it. As with other new technologies, such as information technology, small, entrepreneurial firms will be the source of much of the innovation and commercialization in agricultural biotechnology. Venture capital will materialize, but only in the right business climate. It is imperative, therefore, that we do not throw up unwarranted regulatory roadblocks that would reduce the value of this research and dry up private-sector investment. Important

intellectual property issues also will have to be addressed if we are to reap the full potential of this research.

REGULATION

Recommendation: Federal regulatory oversight of agricultural biotechnology should be risk-based and guided by the characteristics of the plant, its intended use, and the environment into which it is to be introduced, not by the method used to produce it. Existing regulations at USDA and proposed regulations at EPA targeting the products of biotechnology do not conform with the scientific consensus and should be revised to stay current with advances in scientific knowledge.

Oversight should be commensurate with risk. The overwhelming view of the scientific community—included in reports by NAS, NRC, OECD, 11 professional scientific societies, and CAST—is that plants and plant-derived foods developed using biotechnology do not pose risks different from those for similar plants developed using traditional methods of genetic manipulation. The conclusion of these scientific bodies is that regulatory oversight should focus on characteristics of the product, not process by which it was produced. This principle also was accepted by OSTP and the regulatory agencies in their Statement on Scope—which provided regulatory agencies guidance on the application of discretionary authority under existing statutes—and it forms a scientifically-sound basis for regulation to ensure the safety of new plant and food varieties both to human health and the environment.

The present situation facing USDA, EPA, and FDA in dealing with agricultural biotechnology is analogous in many respects to the situation faced by the Federal Communications Commission (FCC) when it dealt with the issue of data transmission over telephone lines in the mid 1960s. A recent analysis of the FCC's role in creating an environment in which the Internet could flourish said, "Predicting that the future would bring the convergence and interdependence of computers and communications, the Commission recognized the difficulty of separating the two into discrete categories" (Oxman, 1999). In 1971, the FCC adopted a policy that data transmission would be treated no differently than voice transmission. The decision not to throw up new regulatory roadblocks for data transmission was extremely important in spurring subsequent development of the Internet.[67]

For regulatory purposes, the distinctions among traditional plant breeding, wide-hybrid crossing, mutagenesis, and rDNA methods in crop improvement are as conceptually artificial as those once suggested for voice and data transmission. The history of crop improvement over the 20th century suggests that biotechnology is just the latest in a continuum of technological innovations that have enhanced agricultural productivity enormously.

The Coordinated Framework foresaw that federal regulations would need to be modified to reflect increased understanding of the risks of rDNA technologies. "The regulatory framework anticipates that that future scientific developments will lead to further refinements," it said, adding that "evolution is anticipated in the regulation of commercial products as scientists and

[67] In Europe, regulators have treated voice and data transmissions differently. This has slowed the growth and development of data networks, and many European networks now are outmoded.

regulators learn to predict more precisely particular product use that require greater or lesser controls or even exemption from any federal review" (OSTP, 1986).

A wealth of information has been amassed by the scientific community and the regulatory agencies on agricultural biotechnology. We now have 25 years of experience worldwide, an extensive record of field trials overseen by USDA and EPA (over 5,000 at USDA alone), and over a decade's worth of analyses by FDA on a broad range of biotechnology products. This vast body of knowledge and experience has demonstrated the substantial equivalence of plants produced using traditional breeding and rDNA methods.

Today, it often costs hundreds of millions of dollars to develop a new plant variety using biotechnology, much of which is related to meeting regulatory requirements. These costs largely outweigh the advantages of using recombinant techniques. There is a genuine concern that persisting with current, and imposing new, regulatory restrictions may harm an emerging industry and the publicly-funded university research base on which it depends.

Further, there are indications that EPA and USDA policies that result in selective regulation of rDNA-modified plants have been used against the United States by EU countries in international negotiations. It is difficult for the Administration to argue in international venues that international agreements should adhere to accepted scientific norms if those same norms are not applied consistently in the domestic sphere.

For these reasons, the Administration should begin work to eliminate artificial regulatory distinctions based on the method by which a new plant or food variety is produced or the source of the gene that has been transferred. In addition, agencies should make better use of the effective nonregulatory oversight mechanisms, including scientific peer review, that have been developed over many years. More specifically, USDA's interpretation of the Plant Pest Act and EPA's proposed plant pesticide rule, each of which effectively singles out some plants based on their method of production, should be modified to reflect the risk-based principles accepted by the scientific community.

USDA Plant Pest Regulations

USDA should revise regulations that target biotech plants based on the source of the genetic material, the vector used to transfer it, or the regulatory sequences used to express it. After thousands of successful field trials and years of scientific research, there is no reason to continue under the assumption that transferring a gene from a plant pest to a crop plant poses an environmental hazard.

The scientific evidence is clear that the method used to introduce or express a transferred gene is a poor indicator of risk. USDA's notification procedure for field-test permits for certain regulated articles is a step in the right direction, but plant breeders are still subject to rigorous testing, monitoring, and reporting requirements that add unnecessarily to the costs of developing a new plant variety using biotechnology. USDA should consider developing risk-based guidelines similar to those employed by FDA, which have been effective in getting new products to market quickly and safely.

EPA Proposed Plant Pesticide Rule

EPA's proposed plant pesticide rule would use sexual compatibility or novelty—*i.e.*, the source of the gene—as justification for initiating regulatory oversight. The testimony and other material made available to the Subcommittee, particularly the reports of 11 professional scientific societies and CAST, make a strong case that novelty is not synonymous with risk and that EPA's approach is not scientifically valid.

In its present form, the proposed regulatory requirements would apply when a gene encoding for a pesticidal substance from one plant is transferred to another, sexually-incompatible plant—even when the donor plant has a history of safe use. As our knowledge of plant genomics advances, it is not hard to imagine a situation in which a plant is regulated because the gene encoding for plant pesticide was transferred from a sexual incompatibility organism only to discover subsequently that the same or similar gene is found in a wild relative of the regulated plant. Moreover, EPA is on scientifically shaky ground in exempting a rDNA plant where the pest-resistant trait is transferred from a sexual compatible plant.

The basis of EPA's proposed rule—that sexual incompatibility or novelty indicate increased risk and sexual compatibility indicates decreased risk—is not a scientifically-sound one for regulation. As NAS said in 1987, "There is no evidence that a gene will convert a benign organism into a hazardous one simply because the gene came from an unrelated species," and there has been no information developed in the intervening years to cast doubt on that conclusion. Therefore, EPA should reconsider its current proposal and develop new rules consistent with the scientific consensus on risk, the Statement on Scope, and a single approach to plant breeding involving biological pest resistance, regardless of the genetic method used. Risk-based guidelines on pest-protected plant analogous to those employed by FDA in its Statement of Policy should be developed.

VOLUNTARY CONSULTATION AT FDA

Recommendation: FDA should maintain its current science-based policy of equating foods developed using biotechnology and classical plant breeding methods, and it should maintain its policy of voluntary consultation with companies developing foods using genetic modification, regardless of the method employed.

Critics of agricultural biotechnology, particularly those in Europe, have derided FDA's oversight policy as "voluntary." This criticism rests on the mistaken presumption that foods derived from biotech plants pose greater risks than traditional foods and that current oversight practices are not adequate to protect public safety. There is no scientific evidence to support either of these contentions. Mandatory consultation would not enhance public safety, but would saddle taxpayers and consumers with additional costs.

Current FDA policy regarding food additives—for foods created through either traditional or rDNA methods—states that food additives already require pre-market approval unless they are recognized as safe on the basis of a history of safe use in the food supply or scientific analysis.

Under FDA policy, plant-food developers (using either traditional or biotech methods) are allowed to make this determination.

To date, all companies that have brought a food derived from bioengineered plants to market have participated in the voluntary consultation process. But even in the absence of such consultation, there is no reason to believe that the safety analyses performed by the food producer are not rigorous. Critics of this technology often overlook or dismiss as insufficient the legal duty of food producers, rather than FDA, to ensure the safety of the foods they bring to market. FDA has broad post-market enforcement powers, including criminal prosecution. These facts, as well as the ever-present threat of civil action by consumers who claim to have suffered harm as the result of eating an unsafe food product, is strong inducement for companies to produce safe, wholesome foods.

FDA needs to be more forceful in standing by and explaining its regulatory decisions. That America's food supply is among the safest in the world demonstrates that current regulatory oversight, applied to a remarkable and expanding array of plant-derived food products, is more than adequate to protect human health. Therefore, Congress should reject legislative proposals that would make the voluntary consultative process at FDA mandatory.

LABELING

Recommendation: FDA should maintain its current science-based policy on labeling of foods created using biotechnology as described in its 1992 Statement of Policy. There is no scientific justification for special labeling of food products developed using agricultural biotechnology, as a class.

Current FDA policy, based on its 1992 Statement of Policy, states that foods should be labeled according to their characteristics, and not their method of production. This policy is consistent with the Statement on Scope and the scientific consensus on the risk of plant-derived foods developed using biotechnology. Testimony before the Subcommittee from both FDA and independent research scientists confirms that this policy is scientifically sound and protects consumer interests.

FDA's policy mandates that substances that are added to biotech foods must be regulated—and labeled—as additives unless it is determined that these substances are "generally recognized as safe." The same standard applies to all food additives, regardless of their origin. The FDA has indicated clearly that biotech foods containing allergens or toxins, or those that are substantially different nutritionally from current varieties, must carry a label to this effect. This is appropriate from a scientific perspective and has been effective in protecting human health.

It should be noted that producers are free to label the foods they produce as free of genetic modification through rDNA techniques. In contrast, it would be misleading to label the products of conventional plant breeding as being free of genetically-modified substances. Moreover, there is no scientific justification to impose the costs of segregation and identity preservation on all farmers, food processors, and distributors simply because new genetic methods were used in food production. Market forces will signal the degree to which producers and suppliers select

labeling or identity preservation. As more foods are developed with enhanced nutrient, taste, or other characteristics that consumers want, food producers likely will both label their products accordingly and actively advertise them and their enhancements.

FDA's current policy on labeling is scientifically and legally sound and should be maintained. Legislation mandating the labeling of food products derived from agricultural biotechnology would raise costs to consumers and discourage the development and marketing of new, beneficial biotech products. Congress should oppose mandatory labeling legislation.

INTERNATIONAL AGREEMENTS

Recommendation: The Administration should work to ensure that markets for products of agricultural biotechnology products are not restricted by scientifically unsound measures. The United States should not accept any international agreements that violate scientific principles and limit trade in, or mandate labeling of, a plant or food product based on the method used to develop it.

Unfounded fears about biotechnology and, in some cases, simple economic protectionism have led some nations to impose restrictions on biotechnology products, costing American farmers hundreds of millions of dollars and disrupting fair U.S. access to export markets. Congress and the Administration should work to ensure that international markets for agricultural biotechnology products are not harmed. The Administration, in particular, needs to take the lead role in explaining and defending the extraordinary record of safe use of biotechnology products that has been built up over many years.

The United Nations Convention on Biodiversity, which stemmed from the 1992 Earth Summit in Rio de Janiero, recently met in Montreal and announced on January 29, 2000 a new protocol (Biosafety Protocol) covering the "transboundry movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity" (UNEP, 2000).[68] The Biosafety Protocol—which strictly speaking is an environmental agreement, not a trade agreement—allows a country to require prior notification from countries exporting biotech seeds and living organisms that are intended to be introduced into the environment. In addition, it requires that shipments of products that may contain living modified organisms (such as bulk commodities for food, feed, or processing) be identified as such.

Many delegates to the Montreal negotiations also wanted the agreement to supercede WTO's Sanitary Phytosanitary Standards, which require health and sanitary restrictions to have a scientific basis. Both the State Department and the U.S. Trade Representative have made assurances that the superiority of the WTO standards is maintained in the agreement.

The Biosafety Protocol has been interpreted by some observers as implicitly endorsing the precautionary principle, although it is not mentioned specifically in the document. This principle maintains that, at the political level, governments may implement measures to restrict a product if there is any perceived uncertainty about risk. As the testimony shows, science can never

[68] The agreement does not cover processed foods or pharmaceuticals.

demonstrate zero risk. Therefore, risk assertions may be considered by a government to justify trade restrictions, even where there is no credible scientific evidence that a risk exists. The European Union maintains that invoking the precautionary principle is an "eminently political decision" that "may be based on a less objective appraisal" (EU, 2000).

Set against the political nature of the precautionary principle is the scientific consensus that risk assessment should focus on probable, not hypothetical, risks. Historically, the United States has not endorsed the precautionary principle as a basis for regulatory decisions. Doing so would completely undermine the science-based regulatory structure that has relied on a cautious approach in the scientifically-objective assessment of risk, which has served the Nation well for decades.

The United States has not ratified the Convention on Biological Diversity and was not an official participant in the Montreal talks. Nevertheless, the Administration has said it will abide by the agreement. Some analysts have suggested that, by pledging to accede to the Biosafety Protocol, the Administration appears to have given tacit approval to the idea that the products of agricultural biotechnology are intrinsically different from traditionally-produced foods—a view the scientific community roundly rejects.

While interpretations of the agreement differ, there is near unanimity that it does not impinge on U.S. trade rights. However, questions remain on how it will be implemented. Of perhaps even greater concern is that the Biosafety Protocol could be used by opponents of biotechnology to create mischief in other international venues, particularly WTO and the FAO and WHO standards commission, which oversees the Codex Alimentarius, the international food code.

The concept of substantial equivalence as a basis for regulation of agricultural biotechnology has been accepted by a number of international bodies, including OECD, WHO, FAO, and the International Life Sciences Institute. Moreover, WTO rules require a scientific basis for restrictions on agricultural products related to health and safety.

Adoption of the precautionary principle by FAO and WHO could have a devastating effect in U.S. trade and scientific interests. Annually, U.S. farmers—the most efficient in the world—sell about $50 billion of goods in international markets. Treaties or other international obligations that undermine the concept of substantial equivalence and WTO rules will hurt U.S. farmers, academic researchers, the biotechnology industry, and consumers.

The United States, as the world leader in biotechnology, has an obligation to demonstrate leadership and resist false scientific premises both at home and abroad. In addition to revising U.S. regulations, the Administration should actively oppose international agreements that do not meet scientific principles and that penalize the products of agricultural biotechnology. To accept less will only encourage the injection of even more protectionist politics into international agreements and harm U.S. interests.

PUBLIC EDUCATION

Recommendation: The Administration, industry, and scientific community have a responsibility to educate the public and improve the availability of information on the long record of safe use of agricultural biotechnology products and research activities.

Testimony before the Subcommittee indicated concern about the spread of misinformation and the lack of public access to accurate information about technical advances in biotechnology. Both reinforce irrational fears about biotechnology.

The evidence that the risks associated with traditional and rDNA techniques for plant breeding are equivalent is overwhelming. However, policymakers and the public are largely unaware of the vast information and findings gathered by the regulatory agencies and eminent scientific bodies over the 25 years that rDNA technologies have been developed and widely used. In her testimony before the Subcommittee, Dr. Salyers said, "I think what we really need is some sort of a public education initiative . . . We really need to inform consumers about this, because otherwise I think there are going to be some very bad decisions made for the wrong reasons."

The regulatory agencies have not been as active in the public debate as they could, given the substantive knowledge they have to share on the subject of risk. The Administration has an obligation to ensure that information about the application of agricultural biotechnology is disseminated widely. Some information already is available—for example, USDA, EPA, and FDA have developed a coordinated Website for information on regulations. But there is no comparable site for the considerable biosafety information and scientific analyses they have compiled over the many years in which they have been regulating the products this technology. Individual agency Web pages do provide some of this information, but much of it is highly technical and geared towards specialists, and thus is difficult for the general public to interpret.

The Administration should instruct USDA, EPA, FDA, NIH, and NSF to develop, in consultation with OSTP, a coordinated Web-based system to provide public access to pertinent, factual information on plant genomics and agricultural biotechnology. Each of these agencies should convey—in terms understandable to the general public—its experience in researching and regulating this technology: USDA and EPA for field trials; FDA on the principles and structure of its risk-based policies; NIH on rDNA research; and NSF and USDA on plant genomics. Information also should be provided explaining the historical mechanisms, including nonstatutory oversight by professional and scientific bodies, used to ensure the safety of the U.S. food supply over the past five decades.

The biotechnology industry also needs to be more forceful in its defense of biotechnology. For years the industry has played by the rules to bring new, safe products to market. U.S. companies have spent hundreds of millions of dollars of research and development capital and have conducted years of rigorous testing and evaluation required by USDA, EPA, and FDA regulations. Biotechnology companies have been held to a high level of accountability and possess an outstanding record of safety. Consumers need to know this.

In fulfilling their responsibilities to shareholders, farmers, and consumers, biotechnology companies need to add their voices to the debate. Specifically, they need to address the purpose and benefits of their products on the market and in development. They should use familiar

products produced using traditional methods to provide consumers a familiar context for making comparisons.

Lastly, independent scientists—like those who appeared before the Subcommittee—need to take a more active role in explaining their work to the public, especially the research that will lead to improvements in human health and help feed a growing world population. Scientists working in plant genomics and agricultural extension at Land Grant colleges are particularly well-suited to provide this sort of information. Scientific organizations also have a role to play. The reports of NAS, NRC, 11 scientific societies, and CAST, cited throughout this report, are particularly good examples of how professional organizations can aid policymakers. Expanded efforts should be directed to educating the general public.

For many scientists, this can be a burden that takes time away from research. However, the issues are so important that they need to make a special effort to become more involved. They should make themselves available to the press and legislators and speak at civic organizations. Participation on government panels that review biotechnology issues also is encouraged.

It has been said that "Error is a hardy plant: it flourisheth in every soil."[69] In the debate over agricultural biotechnology, the stakes are too great to allow the error and misinformation that have flourished in Europe to take root here. By engaging the critics and making information available to the public, regulators, plant developers, and researchers can address Dr. Salyers's concern and help consumers and policymakers make good decisions for the right reasons.

[69] Martin Tupper, *Proverbial Philosophy (1838-1842), Of Truth in Things False.*

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APPENDIX 1: LIST OF FINDINGS AND RECOMMENDATIONS

Findings

The Report makes the following findings:

Plant Genome Research. The plant genome program represents a sound use of federal research funding

Chemical Inputs. The current generation of pest-resistant and herbicide-tolerant agricultural plants produced using biotechnology has reduced chemical inputs and improved yields for American farmers. Future adoption of new varieties will continue this trend and will solve intractable pest problems, help protect the environment, and lower costs to consumers.

Consumer Benefits and Global Food Production. The promise of agricultural biotechnology is immense. Advances in this technology will result in crops with a wide range of desirable traits that will directly benefit farmers, consumers, and the environment and increase global food production and quality.

Assessing Risks. There is no evidence that transferring genes from unrelated organisms to plants poses unique risks. The risks associated with plant varieties developed using agricultural biotechnology are the same as those for similar varieties developed using classical breeding methods. As the new methods are more precise and allow for better characterization of the changes being made, plant developers and food producers are in better position assess safety than when using classical breeding methods.

Outcrossing. The risks that new plant varieties developed using agricultural biotechnology will become weedy or outcross are the same as those for similar varieties developed using classical breeding methods and for introduced species.

Pest-Resistant Crops and the Potential for Pesticide-Resistant Insects. Widespread use of pest-resistant crop varieties developed using agricultural biotechnology is unlikely to accelerate the emergence of pesticide-resistant insect strains and may actually be more effective in preventing their emergence when compared to spray applications of similar pesticides.

Monarch Butterfly. The threat posed by pest-resistant crop varieties developed using agricultural biotechnology to the Monarch butterfly and other non-target species has been vastly overblown and is probably insignificant.

Allergens and Toxins. The risks of introducing an allergen or toxin into the food supply are the same for plant varieties developed using agricultural biotechnology as those for similar varieties developed using classical breeding methods.

Antibiotic Resistance. The risk that a health hazard will be created through the use of antibiotic resistance markers in the development of new plant varieties using agricultural biotechnology is insignificant.

Substantial Equivalence. The concept of "substantial equivalence" in the regulation of foods developed using agricultural biotechnology is scientifically sound and provides a useful historical baseline for judging safety.

Labeling. There is no scientific justification for labeling foods based on the method by which they are produced. Labeling of agricultural biotechnology products would confuse, not inform, consumers and send a misleading message on safety.

Oversight. Federal regulations should focus on the characteristics of the plant, its intended use, and the environment into which it will be introduced, not the method used to produce it. Regulations that capture selectively the products of agricultural biotechnology do not reflect the scientific consensus on risk, are overly burdensome, and stifle scientific research.

Politically-Motivated Opposition. Much of the opposition to agricultural biotechnology is not scientifically based.

Recommendations

The Report makes the following recommendations:

Plant Genome Research. Congress should ensure adequate levels of funding for the National Plant Genome Initiative. Efforts to link basic research in plant genomics with local plant breeding programs at Agricultural Experiment Stations and with Cooperative Extension should be increased.

Regulation. Federal regulatory oversight of agricultural biotechnology should be risk-based and guided by the characteristics of the plant, its intended use, and the environment into which it is to be introduced, not by the method used to produce it. Existing regulations at USDA and proposed regulations at EPA targeting the products of biotechnology do not conform with the scientific consensus and should be revised to stay current with advances in scientific knowledge.

Voluntary Consultation at FDA. FDA should maintain its current science-based policy of equating foods developed using biotechnology and classical plant breeding methods, and it should maintain its policy of voluntary consultation with companies developing foods using genetic modification, regardless of the method employed.

Labeling. FDA should maintain its current science-based policy on labeling of foods created using biotechnology as described in its 1992 Statement of Policy. There is no scientific justification for special labeling of food products developed using agricultural biotechnology, as a class.

International Agreements. The Administration should work to ensure that markets for products of agricultural biotechnology products are not restricted by scientifically unsound measures. The United States should not accept any international agreements that violate

scientific principles and limit trade in, or mandate labeling of, a plant or food product based on the method used to develop it.

Public Education. The Administration, industry, and scientific community have a responsibility to educate the public and improve the availability of information on the long record of safe use of agricultural biotechnology products and research activities.

APPENDIX 2: ACRONYMS

APHIS	Animal and Plant Health Inspection Service
BMA	British Medical Association
Bt	*Bacillus thuringiensis*
CAST	Council on Agricultural Science and Technology
DNA	deoxyribonucleic acid
DOE	Department of Energy
EDF	Environmental Defense Fund
EPA	Environmental Protection Agency
ERS	Economic Research Service
EU	European Union
EUP	Experimental Use Permit
FAO	United Nations Food and Agricultural Organization
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GM	genetically modified
GMO	genetically modified organism
GRAS	generally recognized as safe
HIV	Human Immunodeficiency Virus
IFT	Institute of Food Technologists
IWG	Interagency Working Group on plant genomics

NAS	National Academy of Sciences
NIH	National Institutes of Health
NPGI	National Plant Genome Initiative
NRC	National Research Council
OECD	Organisation of Economic Co-operation and Development
OSTP	Office of Science and Technology Policy
rDNA	recombinant DNA
SAES	State Agricultural Experiment Stations
SCEC	Select Committee on the European Communities
UNICEF	United Nations Children's Fund
USDA	United States Department of Agriculture
USGS	United States Geological Survey
WHO	World Health Organization

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